

EXHIBIT A

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(Cite as: Not Reported in F.Supp.)

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Go Medical Industries Pty, Ltd. v. C.R. Bard, Inc.
N.D.Ga., 1995.

United States District Court, N.D. Georgia.
GO MEDICAL INDUSTRIES PTY, LTD., Plaintiff-
Counterclaim Defendant

v.

C.R. BARD, INC., Defendant-Counterclaimant
Civ. A. No. 1:93cv-1538-HTW.

July 6, 1995.

ORDER OF COURT

HORACE T. WARD, Senior District Judge:

*1 This matter is currently pending before this court on the following motions: (1) Medical Marketing Group, Inc.'s ("MMG")^{FN1} motion to quash subpoena or in the alternative for protective order; (2) plaintiff's motions for a protective order; (3) defendant's motions to compel discovery, and (4) defendant's motion for leave to amend answer.

BACKGROUND

This case is a patent infringement suit brought by plaintiff against defendant. The patent-in-suit is U.S. Patent No. 4,652,259 ("the '259 patent"), which relates to urinary catheters. Said patent issued on the fourth application. The first application was filed on September 12, 1979, but was subsequently abandoned. At approximately the same time, plaintiff allegedly filed a continuation application; this application also was abandoned and another continuation application was filed on March 21, 1985. The '259 patent issued on March 24, 1987.

On June 8, 1993, plaintiff filed a petition with the U.S. Patent Office to revive this first application. Defendant claims that -- in order to obtain the September 12, 1979 filing date -- 37 C.F.R. § 1.183 dictates that this petition had to be filed within three (3) months after the applicant became aware of the abandoned status of the application. In support of the petition, B.J. Powell, plaintiff's counsel, filed an affidavit stating that he was first notified of the abandonment -- that is, the lack of copendency between the first and

second applications -- "on or about March 8, 1993."

Three of the above motions relate to defendant's discovery requests, in which defendant seeks, *inter alia*, information regarding plaintiff's knowledge of a lack of copendency between plaintiff's first and second patent applications.^{FN2} More specifically, defendant seeks information to determine whether plaintiff became aware of this lack of copendency prior to March 8, 1993. Plaintiff asserts that the information requested by defendant is protected by the attorney-client and/or work-product privileges. Defendant argues that these privileges do not allow plaintiff to withhold this information from defendant.

DISCUSSION

A. Medical Marketing Group, Inc.'s Motion To Quash Subpoena Or In The Alternative For Protective Order; Plaintiff's Motions For A Protective Order

MMG moves this court for an order quashing a subpoena served by defendant on MMG requesting production of documents relating to "any comparisons between the MMG-O'Neil urinary catheters and the Bard Touchless catheters."^{FN3} MMG claims that the requested information is protected by the attorney-client and/or the work product privileges. However, other than a videotape, MMG has failed to specifically identify any documents for which it asserts the above privileges. Moreover, MMG has cited no case law or other authority in support of its motion, other than a general reference to Fed.R.Civ.P. 45.

This court agrees with defendant that MMG has failed to carry its burden that the requested information is privileged. See United States v. Schaltenbrand, 930 F.2d 1554, 1562 (11th Cir.), cert. denied, 112 S. Ct. 1348 (1993). Nor has MMG sufficiently described the withheld documents, as required by Fed.R.Civ.P. 26(b)(5) and 45(d)(2), so as to allow defendant to contest the privilege claim on a document-by-document basis.

*2 With respect to the attorney-client privilege, MMG has failed to show that "the communication was made to him confidentially, in his professional

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capacity, for the purpose of securing legal advice or assistance.” *Id.* (citation omitted). MMG also has neglected to show, as it is required to show, that the privilege has not been waived. Weil v. Investment/Indicators, Research and Management, Inc., 647 F.2d 18, 25 (9th Cir. 1981). While the privilege is construed narrowly, waiver of the privilege is applied broadly. United States v. Moody, 763 F. Supp. 589, 597 (M.D.Ga. 1991), *aff’d*, 977 F.2d 1240 (11th Cir. 1992), *cert. denied*, 112 S. Ct. 640 (1991). This court concludes that MMG has failed to carry its burden of showing that any of the requested documents are within the attorney-client privilege; thus, MMG must produce these documents.

In addition, MMG claims that a videotape is subject to the work-product privilege under Fed.R.Civ.P. 26(b)(3), thus this court should not compel its production. In its reply memorandum, MMG makes the assertion that the videotape was prepared at counsel's request in anticipation of litigation; MMG has not offered an affidavit or any other evidence to support its claim of work-product privilege.^{FN4} See Fed.R.Civ.P. 26(b)(3). This court concludes that MMG shall, within ten (10) days of their receipt of this Order, produce the videotape at issue under seal to this court, which will make an *in camera* review of the videotape before determining whether it should be produced to defendant.

MMG also requests, in the alternative, that this court issue a protective order (1) limiting the depositions of Messrs. Golden and Starke to the issue of defendant's alleged infringement of the MMG O'Neil catheter, and (2) limiting the documents produced by these individuals to those documents not subject to the work-product privilege. MMG offers no support for this protective order, thus this court will not grant plaintiff's request.^{FN5}

Plaintiff also moves this court for a protective order prohibiting disclosure of documents, testimony, and other information in the possession of The Connecticut Indemnity Company (“TCIC”). Plaintiff claims that this information is protected by the attorney-client and/or work-product privileges. TCIC is not a party to this action, but instead an insurer with whom plaintiff has a patent enforcement litigation expense

policy. Plaintiff claims that, based on the “common interest rule”, information in TCIC's possession is privileged -- more specifically, that plaintiff and TCIC have a common interest arising from TCIC's patent enforcement litigation expense insurance policy in favor of plaintiff. Under that policy, TCIC pays certain litigation expenses. Defendant emphasizes that TCIC is not obligated for any liability incurred by plaintiff.

Plaintiff has the burden of establishing a common interest with TCIC. United States v. Gotti, 771 F. Supp. 535, 545 (E.D.N.Y. 1991). In general, the common interest rule “serves to protect the confidentiality of communications passing from one party to the attorney for another party where a joint defense effort or strategy has been decided upon and undertaken by the parties and their respective counsel.” United States v. Schwimmer, 892 F.2d 237, 243 (2nd Cir. 1989). See also In re Bairco Corp. Securities Litigation, 148 F.R.D. 91, 102 (S.D.N.Y. 1993) (joint defense privilege protects communications from one party to another). The Seventh Circuit has limited the common interest rule to “parties or potential parties to an action.” Russell v. General Electric Co., 149 F.R.D. 578, 580 (N.D.Ill. 1993).

*3 In support of its “common interest” argument, plaintiff cites In the Matter of Grand Jury Subpoena Duces Tecum, 406 F. Supp. 381 (S.D.N.Y. 1975).^{FN6} In that case, the court found “that the attorney-client privilege covers communications to a prospective or actual co-defendant's attorney when those communications are engendered solely in the interests of a joint defense effort.” *Id.* at 389. This case involved communications made during interviews intended to promote the joint defense of various individuals.

Plaintiff has failed to cite any cases where, as here, a party asserts the common interest rule applies to an insurance company that merely pays a party's litigation expenses (as opposed to liability). This court finds that the cases cited by plaintiff are neither persuasive nor binding on this court.

This court believes the case at bar is more analogous to North River Insurance Co. v. Philadelphia Reinsurance Corp., 797 F. Supp. 363 (D.N.J. 1992). In

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North River, the court found that an insurer-insured relationship "does not fall within the confines of the classic common interest doctrine" because the insured retained its own counsel wholly independent from the insurer, and the insurer had no input into, or control of, the relationship between the insured and the insured's counsel. *Id.* at 367. Similarly, both plaintiff and TCIC had their own counsel; TCIC did not control plaintiff's relationship with plaintiff's counsel.^{FN7}

Further, plaintiff has not carried its burden of showing that the requested information was privileged -- for example, intended to be confidential. Nor has plaintiff demonstrated that it has not waived the attorney-client privilege. Therefore, plaintiff is not entitled to the requested protective order.^{FN8}

B. Defendant's Motions To Compel Discovery

In response, defendant moves this court for an order compelling Messrs. Golden and Starke of MMG to produce requested documents and appear for a deposition. As stated above, MMG shall produce all the requested documents to defendant, with the exception of the videotape, which shall be filed with this court for an *in camera* review. In addition, MMG does not oppose defendant's request to take the above depositions.^{FN9}

Defendant also moves this court for an order compelling plaintiff to provide responses to defendant's Interrogatory Nos. 2, 3, 5, and 6, and Document Request Nos. 7, 8, and 18. Plaintiff claims that this information already has been produced. Defendant argues that plaintiff has failed to identify each document that it seeks to withhold from production and has failed to make a specific claim of privilege for each such document. Instead, it appears as though plaintiff has made a blanket claim of privilege, which is improper. *Schachar v. American Academy of Ophthalmology, Inc.*, 106 F.R.D. 187, 193 (N.D.Ill. 1985); *In re Shopping Carts Antitrust Litigation*, 95 F.R.D. 299, 305 (S.D.N.Y. 1982).

Defendant also argues that, assuming *arguendo* that plaintiff's claim of privilege extends only to those documents identified in TCIC's privileged document

list, plaintiff has not shown that these documents are privileged. Plaintiff relies on the so-called "common interest doctrine" in order to assert the attorney-client privilege to the extent that TCIC could utilize the privilege.

*4 As stated in Section A., *supra*, plaintiff has not shown that the common interest rule applies or that these documents are otherwise privileged.^{FN10} Therefore, this court GRANTS defendant's motions to compel discovery.

C. Defendant's Motion For Leave To Amend Answer

Defendant moves this court pursuant to Fed.R.Civ.P. 9(b) and 15(a) for leave to file an amended answer -- namely, to add new allegations of inequitable conduct by plaintiff. It is well-established that Rule 15(a) should be construed liberally, and leave to amend should be granted freely when justice so requires. *Shipner v. Eastern Air Lines, Inc.*, 868 F.2d 401, 407 (11th Cir. 1989). Nevertheless, leave to amend is not a matter of right, and in deciding whether to grant leave to amend, the court should consider factors such as undue delay, bad faith or dilatory motive on the part of the movant, the prejudice which would result to the non-movant, and the futility of the amendment. *Rosen v. TRW, Inc.*, 979 F.2d 191, 194 (11th Cir. 1992).

Defendant states that the new allegations of inequitable conduct is based on newly discovered facts learned by defendant during discovery.^{FN11} More specifically, defendant claims that it has learned that (1) plaintiff was informed of a lapse in copendency between the first and second filed applications in August 1992, and (2) plaintiff's counsel, B.J. Powell, stated that he was informed of this lack of copendency "on or about March 8, 1993" -- so as to appear to fall within the three-month period under 37 C.F.R. § 1.183 -- when in fact he learned this at least as early as March 5, 1993. Further, defendant contends that any delay in uncovering the above facts is due to plaintiff's attempts to block defendant's discovery efforts.

In response, plaintiff claims that defendant has known about the alleged facts supporting its motion

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since September 1994, thus defendant failed to move to amend its answer within a reasonable time. While defendant may have obtained some information to support its new allegations in September of 1994, this court will not penalize defendant for obtaining additional, confirming information in January 1995 to support its claims -- especially given that Rule 9(b) requires that allegations of fraud, such as inequitable conduct before the U.S. Patent Office, be stated with particularity.

Plaintiff also claims that it would be substantially prejudiced if defendant's motion (filed at the close of discovery) was granted, as plaintiff would be unable to conduct discovery regarding these new allegations. This court is not persuaded by this argument either. Plaintiff has not indicated the type of discovery it would desire undertake if defendant's motion is granted; in addition, plaintiff does not claim that defendant possesses any documents or other information that would be relevant to its claims that plaintiff acted inequitably. ^{FN12}

This court concludes that Rule 15(a) and applicable case law dictate that defendant should be allowed to amend its answer. Plaintiff has not shown that the amendment would cause undue delay, would prejudice plaintiff, or would be futile. Nor has plaintiff shown bad faith or dilatory motive on the part of defendant. Thus, this court GRANTS defendant's motion for leave to amend answer.

CONCLUSION

*5 Therefore, after due consideration, this court (1) DENIES Medical Marketing Group, Inc.'s motion to quash subpoena or in the alternative for protective order; (2) DENIES plaintiff's motions for a protective order; (3) GRANTS defendant's motions to compel discovery; and (4) GRANTS defendant's motion for leave to amend answer. ^{FN13}

SO ORDERED. ^{FN14}

^{FN1} Medical Marketing Group, Inc. is the United States licensee for plaintiff, an Australian medical company. Where appropriate, both entities shall be referred to collectively as "plaintiff."

^{FN2} Plaintiff also has introduced evidence that there were two "gaps" in the '259 patent.

^{FN3} At the outset, this court notes that MMG has failed to comply with this court's local rules, which require that all motions be accompanied by supporting memorandum of law and, where appropriate, supporting affidavits. See LR 220-1(a)(1), NDGa. Nevertheless, this court will consider MMG's motion.

^{FN4} Counsel's arguments in pleadings do not constitute evidence. In addition, the mere fact that the videotape was made at approximately the same time as plaintiff filed its litigation insurance claim does not dictate that it was prepared in anticipation of litigation.

^{FN5} As stated above, however, this court will make an *in camera* review of the videotape in question, the only document MMG claims is subject to work-product immunity.

^{FN6} Plaintiff also cites an unreported case from the Northern District of Illinois, *In the Matter of Quantum Chemical/Lummus Crest*, 1992 WL 71782 (N.D.Ill.), which involved a declaratory judgment action by an insurer against an insured regarding a coverage dispute.

^{FN7} In addition, the fact that TCIC may be paying plaintiff's attorneys' fees does not necessarily give TCIC a common interest with plaintiff. Cf. *Intern. Insurance Co. v. Newmont Mining Corp.*, 800 F. Supp. 1195, 1196-97 n. 2 (S.D.N.Y. 1992) (addressing "common interest" exception to attorney-client privilege).

^{FN8} In the course of briefing the various discovery motions, plaintiff has made a number of requests for a protective order. In denying plaintiff's formal motion for a protective order, this court is denying all of plaintiff's current requests for a protective

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FN9. MMG requested, though, that this court limit the scope of those depositions. As stated above, though, this court has denied MMG's request.

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FN10. Moreover, to the extent certain information is confidential in nature, plaintiff will be protected by the protective order executed by this court on June 3, 1994.

FN11. For example, defendant claims that the January 11, 1995 deposition of John C. Linderman, the attorney for plaintiff's insurance company, helped form the factual basis for this motion. Defendant also relies on the January 31, 1995 deposition of Nathaniel Humphries.

FN12. Moreover, plaintiff has acknowledged that, other than its British counsel Mr. Norman Patullo, it has taken the depositions "of all those involved." Defendant has consented to allow plaintiff to take the deposition of its British counsel, Mr. Patullo, in Atlanta.

FN13. The clerk of court has listed as a pending motion Michael Joseph Powell's motion to withdraw as attorney for plaintiff. This docket entry (no. 64) actually is a notification that Michael Joseph Powell has left the firm representing plaintiff, the Law Offices of B.J. Powell, to join another firm. The Law Offices of B.J. Powell will continue to represent plaintiff, with B.J. Powell as lead counsel. Thus, the clerk may terminate entry no. 64 on the docket sheet and delete Michael Joseph Powell as attorney of record.

FN14. As a courtesy to the clerk of court, this court advises the clerk that this Order terminates entry nos. 58, 61, 64, 80, 82, 84, 85, and 86 on the docket sheet.

N.D.Ga.,1995.

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EXHIBIT B

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Remington Arms Co., Inc. v. Modern Muzzleloading, Inc.

M.D.N.C., 1998.

Only the Westlaw citation is currently available.

United States District Court, M.D. North Carolina.
REMINGTON ARMS COMPANY, INC., Plaintiff,

v.

MODERN MUZZLELOADING, INC., Defendant.

No. 2:97CV00660.

Dec. 17, 1998.

MEMORANDUM OPINION

OSTEEN, District J.

*1 This matter comes before the court on Defendant's Motion for Leave to Amend Answer And Counterclaim to add the affirmative defense of inequitable conduct pursuant to Fed.R.Civ.P. 15(a).

For the reasons discussed herein, the court will deny Defendant's Motion To Amend Answer And Counterclaim.

I. FACTUAL AND PROCEDURAL BACKGROUND

On June 18, 1997, Plaintiff Remington Arms Company, Inc. (Remington), instituted a lawsuit against Modern Muzzleloading, Inc. (Modern), alleging infringement of its patent No. 5,606,817 ('817 patent). (Compl. ¶ 7.) Defendant timely filed an answer and counterclaim asserting the affirmative defenses of non-infringement and patent invalidity. (Answer & Countercl.)

On August 7, 1998, more than one year after Plaintiff filed its complaint, and after discovery had closed, Defendant filed a Motion For Leave To Amend Answer And Counterclaim to add the affirmative defense of inequitable conduct, formerly known as fraud on the PTO. (Def.'s Mot. Leave Amend Answer & Countercl.) Defendant alleged that Plaintiff committed inequitable conduct by failing to disclose material prior art during the prosecution of the '817 patent. *Id.* Defendant's motion to amend is the matter now pending before this court. ^{FN1}

^{FN1} Plaintiff has filed a Motion To Strike Portions of Defendant's Reply to Plaintiff's Response to Defendant's Motion For Leave To Amend Answer And Counterclaim Or, in the Alternative, Motion For Leave To File Surreply. Assuming without deciding that Defendant's reply raises new evidence, thus violating LR 7.3(h), it does not affect the outcome of the matter. Therefore, Plaintiff's motion to strike will be denied.

II. DISCUSSION

The decision to grant or deny a motion for leave to amend is within the sole discretion of the district court. Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 230, 9 L.Ed.2d 222 (1962). Pursuant to Fed.R.Civ.P. 15(a), however, leave to amend a pleading "shall be freely given when justice so requires." While the Supreme Court has long held that "this mandate is to be heeded," the Court has delineated several factors that might warrant a court's denial of a motion to amend. Foman, 371 U.S. at 182, 83 S.Ct. at 230. Specifically, it has been held that "leave to amend a pleading should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the moving party, or the amendment would be futile." Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir.1986).

Giving all due consideration to the federal rules' liberal policy toward amendment of pleadings, this court finds that Defendant's motion to amend must be denied for the following reasons.

A. Undue Delay in Filing the Motion to Amend.

Plaintiff alleges that Defendant's motion to amend is untimely. Defendant filed its original answer and counterclaim on October 7, 1997. (Answer & Countercl.) Now, more than one year later, Defendant seeks leave to amend to add the affirmative defense of inequitable conduct, after the close of discovery, ^{FN2} and within a short time of the scheduled trial date.

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FN2. Discovery closed on July 30, 1998.
(Response Def.'s Mot. Leave Amend Answer & Countercl. at 2.)

While Defendant contends that there was no undue delay in making the motion to amend, there is evidence in the record indicating that Defendant was aware of the potential prior art as early as May 5, 1998, if not sooner, when Defendant deposed the inventor of the '817 patent, Troi N. Sachse,^{FN3} yet Defendant chose not to file a motion to amend until August 1998, after the close of extensive discovery. See *Toth v. Glazer*, 163 F.R.D. 549 (E.D.Wis.1995) (Motion to amend should be denied where despite knowledge of its defenses the defendant "waited almost two more months before moving to amend its answer.").

FN3. See Response Def.'s Mot. Leave Amend Answer & Countercl. at 4.

*2 Furthermore, there is evidence which suggests that Defendant was aware of the potential prior art which forms the basis for the claim of inequitable conduct as early as March 1998, when Plaintiff filed a second but related patent infringement lawsuit against Modern in this district (Civil Action No. 1:98CV00225). (Response Def.'s Mot. Leave Amend Answer at 4.)

In the second case, Plaintiff's '073 patent cited prior art not disclosed during the prosecution of the '817 patent. Arguably, Defendant was put on notice that Plaintiff's failure to disclose the art during the prosecution of the '817 patent might constitute inequitable conduct. Despite Defendant's knowledge of the potential prior art when Plaintiff filed the second complaint in March 1998, Modern waited until August 1998 to file a motion to amend to add the defense of inequitable conduct. See *6 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure* § 1488 (2d ed. 1990) ("[A] motion to amend should be made as soon as the necessity for altering the pleading becomes apparent. A party who delays in seeking an amendment is acting contrary to the spirit of the rule."). Therefore, Defendant's unnecessary and unjustified delay weighs heavily against permitting the motion to amend.

B. An Amended Answer Would Be Prejudicial to Plaintiff.

This court recognizes that in the Fourth Circuit, "delay alone is not sufficient reason to deny leave to amend" and that "[t]he delay must be accompanied by prejudice, bad faith, or futility." *Johnson*, 785 F.2d at 509-10. The existence of these factors, in the case at hand, in conjunction with Defendant's unwarranted delay, justifies denying leave to amend.

Although Defendant maintains that Plaintiff will not be prejudiced by an amended answer, this court cannot agree. While cognizant of the fact that leave to amend ordinarily is to be liberally granted, amendments of pleadings are particularly inappropriate, absent exceptional circumstances, once discovery has closed. See *Lifescan Inc. v. Polymer Tech. Int'l Corp.*, 35 U.S.P. Q.2d 1225, 1238 (W.D.Wash.1995) (Denying defendant's motion to amend its answer to add the defense of inequitable conduct where "[e]xtensive discovery [had] already occurred and any further discovery ... would jeopardize the current trial date."); see also *Toth*, 163 F.R.D. at 549-50 (Denying motion to amend where discovery had closed since "[a]n amendment here would prejudice the plaintiff either by denying them [sic] discovery or by adjourning the case."); *Elf Atochem N. Am., Inc. v. United States*, 161 F.R.D. 300, 301-02 (E.D.Pa.1995) ("Motion [to amend] is untimely based on the fact that discovery is virtually complete, and trial is looming close.").

To permit Defendant to amend its pleading now would require the court to reopen discovery. Extensive discovery, however, has already occurred and this court has previously granted a one month extension of discovery, in which it specifically stated that no more extensions of discovery would be allowed. (Response. Def.'s Mot. Leave Amend Answer & Countercl. at 2.) In addition, dispositive motions have been filed and a Markman Hearing for claim construction of disputed patent language has just recently occurred. Moreover, a February 16, 1999, trial date has been set, and the court is not willing to further delay the resolution of this matter, especially in light of the fact that both parties have already incurred significant expense and effort in preparing the case for

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trial.

*3 Furthermore, courts have consistently found that "if the amendment substantially changes the theory on which the case has been proceeding and is proposed late enough so that the opponent would be required to engage in significant new preparation, the court may deem it prejudicial." *Elf Atochem*, 161 F.R.D. at 301. Because this court finds that Plaintiff would be prejudiced by Defendant's motion to amend since Plaintiff has not engaged in any discovery with regard to an inequitable conduct defense, the equities clearly tip in favor of denying Defendant's motion.FN4

FN4. Even assuming the court was willing to reopen discovery, which it declines to do, Plaintiff would still be prejudiced by an amended answer since Plaintiff would be forced to incur additional expenses in defending against the allegations and would almost certainly be faced with a delay in trial.

Since the extensive discovery has closed, dispositive motions have been briefed and filed, a trial date is set, and Plaintiff would be unfairly prejudiced, Defendant's assertion of a new affirmative defense, at this late stage of the litigation, is clearly prejudicial and should be denied.

III. CONCLUSION

For the reasons stated above, the court will deny Defendant's Motion for Leave to File Amended Answer And Counterclaim.

An order in accordance with this memorandum opinion shall be filed contemporaneously herewith.

M.D.N.C.,1998.

Remington Arms Co., Inc. v. Modern Muzzleloading, Inc.

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EXHIBIT C

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LifeScan, Inc. v. Polymer Technology Intern. Corp.
W.D.Wash. 1995

United States District Court, W.D. Washington,
at Seattle..

LIFESCAN, INC., a California Corporation,
Plaintiff,

v.

POLYMER TECHNOLOGY INTERNATIONAL
CORPORATION, a Washington Corporation, De-
fendant.

No. C94-672R.

Jan. 3, 1995.

ORDER ON PENDING MOTIONS: SUMMARY
JUDGMENT MOTIONS, MOTION TO AMEND
ANSWERS, AND PRELIMINARY INJUNCTION
MOTION

ROTHSTEIN, District Judge.

*1 THIS MATTER comes before the court on the various motions listed below. Having considered the pleadings filed in support and in opposition to the motions, and having held oral argument, the court finds and rules as follows:

I. BACKGROUND

Plaintiff LifeScan, Inc. ("LifeScan") is a corporation which has developed a home use blood glucose monitoring system which is sold commercially, primarily to persons with diabetes who use it to monitor the level of glucose (sugar) in their blood. The meters sold by LifeScan are called One Touch meters, while the strips sold for use in the meters are called One Touch test strips. LifeScan has sought and received patents for various components of its monitoring system. The patents at issue in the pending motions are as follows: No. 5,304,468, ("the '468 patent"); No. 4,935,346, known as ("the '346 patent"); and No. 5,049,487, ("the '487 patent"). This case concerns claims by LifeScan and defendant Polymer Technology International Corp. ("Polymer") concerning the three above-named patents. Polymer is a corporation which manufactures and sells blood glucose test

strips, called First Choice strips, to be used in the One Touch blood glucose meters made and sold by LifeScan.

LifeScan claims that Polymer is infringing its home-use blood glucose monitoring patents. Polymer has presented various defenses to LifeScan's claims of patent infringement, including allegations that the patents themselves are invalid; that users of the LifeScan meters have an implied license to use Polymer's testing strips; and that LifeScan has misused its patents and therefore Polymer is not liable for infringement. In connection with their various claims and defenses, the parties have filed the following motions which will be addressed below: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103; LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents; Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents; and LifeScan's Motion for Summary Judgment of No Misuse of the Three Patents at Issue. In addition, Polymer has moved to amend its answers to the complaints which give rise to this matter. Finally, LifeScan has moved for a preliminary injunction with respect to the '468 patent.

II. DISCUSSION

A. Summary Judgment Standard

Summary judgment is proper is "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-50 (1986). The moving party bears the initial burden of demonstrating that it is entitled to summary judgment,

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Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986), after which the burden shifts to the non-moving party to show that there is a genuine issue of material fact. Id. at 322-23. "To create a genuine issue of fact, the nonmovant must do more than present some evidence it asserts is disputed." Avia Group Int'l. Inc. v. L.A. Gear California, 853 F.2d 1557, 1560 (Fed. Cir. 1988) (emphasis in original). There must be sufficient evidence presented "favoring the nonmoving party for a jury to return a verdict for that party. If the evidence [of the non-movant] is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50 (1986) (citations omitted); see also Celotex, 477 U.S. at 322-23.

B. The '468 Patent

*2 The following motions relate to LifeScan's '468 patent, which was issued April 19, 1994: LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent; LifeScan's Motion for Summary Judgment of No Implied License for the '468 Patent; Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112; and Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103. The court will address each of these motions in turn.

1. LifeScan's Motion for Summary Judgment of Literal Infringement of the '468 Patent

By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). Through the patent laws, "Congress [has] recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products ..." Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc., 630 F.2d 120, 137 (3d Cir.), cert. denied, 449 U.S. 1014 (1980). LifeScan has the burden of proving infringement by a preponderance of the evidence. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

The parties agree that in order to determine whether or not a patent has been literally infringed, the court follows a two-step process. Autogiro Co. of Amer. v. U.S., 384 F.2d 391, 401 (Ct. Cl. 1967). First, the court must ascertain the proper meaning or interpretation of the patent claims themselves. Id.; see also Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1258 (Fed.Cir. 1989). In construing the claims, the court should consider, if required, the claim language, the other claims, the prior art, the prosecution, and the specification. S.R.I. Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985). "The determination of scope of the claims is a question of law, and [thus,] a dispute respecting that legal issue does not preclude summary judgment." George v. Honda Motor Co., Ltd., 802 F.2d 432, 434 (Fed. Cir. 1986).

After the court has determined the proper meaning or interpretation of the patent claim itself, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 673 (Fed. Cir. 1990). Where the facts underlying the alleged infringement are undisputed, it is the court's function to apply the claims to the accused device. Martin v. Barber, 755 F.2d 1564, 1567 (Fed. Cir. 1985) (citation omitted). If an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. Graver Tank, 339 U.S. at 607.

a. Scope of the '468 Patent Claims

*3 The parties dispute whether the '468 patent claims only the testing strips, and thus is a "product" patent, or whether it is a "method" patent or "combination" patent of the strip and meter. This is an issue of law to be determined by interpreting the claims of the patent.

The claims of the '486 patent are quoted below, as they appear in the patent itself.

What is claimed is:

1. A reagent test strip for use in an apparatus for determining the blood glucose concentration of a sample of whole blood, said apparatus comprising

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optical means for detecting intensity of light at wavelengths of about 635 nm and about 700 nm reflected from at least a portion of said strip by reading the reflectance of at least a portion of said strip; said strip having a porous portion disposed near a distal end of said strip such that the porous portion generally registers with the optical means of the apparatus when the strip is retained by the apparatus during determination of said blood glucose concentration, said porous portion having a sample receiving surface for receiving a sample of whole blood and a testing surface, said porous portion further comprising reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of the concentration of glucose present in said sample, said reagent means comprising chemical reagents selected to produce said change dependent upon the glucose concentration wherein said chemical reagents comprise a dye precursor forming a chromophore indicative of the concentration of glucose present in said sample, said chromophore absorbing light at about 635 nm but not to any significant extent at about 700 nm.

2. The strip of claim 1 wherein said dye precursor comprises 3-methyl-2-benzothiazoline hydrazone hydrochloride and 3-dimethylaminobenzoic acid.

3. The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5.

Claims 1-3, '468 Patent.

Most persuasive to the court on the issue of claim interpretation is the language of the three claims themselves. Claim 1 begins with the words "[a] reagent test strip" while Claims 2 and 3 refer to "[t]he strip of claim 1." It is clear that each claim constitutes a description of the claimed strip, not a claimed method. Each claim provides a detailed description of the makeup and qualities of the claimed strip, not of the method employed in testing blood glucose levels. Claim 1 repeatedly refers to the strip and its characteristics. Mention of the meter in which the strip is used serves to describe certain strip features, not to describe a combination of strip and meter. The mention of the meter apparatus in the first sentence of claim 1 serves to identify the environment in which

the strip will be used, not to create a claim to the method of determining glucose levels in blood or to the combination of strip and meter. See e.g., *Smith Corona Corp. v. Pelikan, Inc.*, 784 F.Supp. 452, 463 (M.D. Tenn. 1992), *aff'd*, 1 F.3d 1252 (Fed. Cir. 1993); see also *In re Stencel*, 828 F.2d 751, 754-55 (Fed. Cir. 1987).

*4 In addition to the language of the claims, i.e. the repeated references to the strips described in claims 1 through 3, the court finds that the prosecution history favors a finding that the '468 patent is directed solely to the strips themselves. The '468 patent arose out of a continuation application which was amended to contain new claims directed to a "reagent strip." In June, 1993, these amended claims were amended again, but still directed to a "reagent test strip." Although this amendment, given the number Claim 55, described the apparatus in which it was to be used, the dependent claims added along with Claim 55 each begins with the phrase "[t]he reagent test strip of claim 55 ..." After considering the amendments of claims 55 through 59, the patent examiner stated that it was "the examiner's position that the claims are directed to a test strip." Additionally, the examiner referred twice more in that communication to "the claimed test strip." Thereafter, LifeScan submitted an amendment canceling prior claims and adding Claim 60 incorporating the limitations of Claim 55. During and after the submission of Claim 60, LifeScan did not dispute the examiner's interpretation of Claim 55 as referring to the strip itself. In addition, Claim 60 added a feature relating to the nature of the chemicals in the strip.

After an initial rejection by the patent examiner, LifeScan conducted an interview with the examiner, during which drafts of new claims 61 and 62 were discussed. The first of the new claims, which later became claim 1 of the '468 patent, was directed to "a reagent test strip for use in an apparatus for determining the blood glucose concentration in a sample of whole blood." The second new claim, which became claim 2 of the '468 patent, was directed to "the strip of" the first claim. Following the interview, LifeScan also submitted a new claim 63, later claim 3 of the '468 patent, which also was directed to "the strip" of the preceding claim. Claim 61, which was later al-

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lowed, contains fewer references to the nature of the apparatus in which the strip is to be used. The references to the apparatus, i.e. the meter, which do exist are merely descriptive of the environment of the intended use of the strip. See e.g. *In re Stencel*, 828 F.2d at 754-55; see also *Smith Corona*, 784 F.Supp. at 463-65. Based on the court's review of the language of the claims and the patent history, the court has determined that, as a matter of law, the '468 patent claims the testing strip and therefore a product, not a method or combination of method and product.

In addition, this court is not persuaded by Polymer's argument that the '468 patent claims are limited to the reagent strip when in place in the meter with a whole blood sample present thereon. This interpretation is simply not supported by the claim language or the claim prosecution.

The court also finds unpersuasive Polymer's arguments concerning the interpretation of claim 3 of the '468 patent, which reads as follows: "The strip of claim 2 wherein the chemical reagents are at a pH of 3.8 to 5." Based on the claim language and the prosecution history, the court finds that the claim language refers to the pH of the chemical reactants in the dry strip, rather than the "pH of all of the chemicals in the strip when it is placed in the meter and a sample of whole blood is applied thereto" as is argued by Polymer.

*5 Finally, based upon the language of the claims and the claim prosecution, the court finds that the language in claim 1 requiring that the porous portion of the strip

compris[e] reagent means for indicating the concentration of blood glucose in said whole blood sample in the presence of optically visible hemoglobin by creating a change in reflectance at said testing surface indicative of the concentration of glucose present in said sample, ...

does not limit the claim to a strip in which the only hemoglobin that can be optically sensed by the apparatus is that which is "in the red blood cells filtered out and held at the surface of the test strip."

Polymer argues that its strip does not meet the ele-

ments of claim 1 because hemoglobin not "in the red blood cells filtered out and held at the surface of the test strip" is optically visible. However, the court disagrees with Polymer's interpretation of the claim language. First, the court finds that there is no indication that the '468 patent claim 1 is limited to a strip in which the only optically visible hemoglobin is that which is in the red blood cells. On this point, the court notes that the patent expressly refers to "blood being analyzed [flowing] through the pores of the matrix" and to "blood ... wet[ting] the polyamide matrix without having an excess liquid penetrate the porous matrix to interfere with the reflectance reading on the opposite side of the matrix." This language indicates that the claim is not limited to hemoglobin inside red blood cells, but rather also encompasses "free" hemoglobin released into the remainder of the sample. Second, even if the claim were limited in the manner alleged by Polymer, Polymer has not asserted that the hemoglobin presence in red blood cells applied to First Choice strips is not "optically visible" to at least some extent by the LifeScan home-use blood glucose meter.

Therefore, after reviewing the claim language, the patent specification, the prosecution history, the expert deposition testimony submitted, and the prior art, the court has determined that the proper meaning or interpretation of the '468 patent is that it is directed to the test strips *per se*, rather than to a method or combination of strip and meter. Additionally, the '468 patent claims refer to the strips themselves and are not limited to the strips when in the apparatus, with whole blood upon them. Finally, the phrase "in the present of optically visible hemoglobin" does not limit claim 1 to a strip in which the only hemoglobin optically visible is that which is in red blood cells filtered out and held at the surface of the test strip.

b. Application of the Claims to Polymer's Test Strip

As noted above, the court has determined that the proper interpretation of the patent claim is that the '468 patent is directed to the test strip itself, not the method of testing blood glucose or the combination of the meter and strip. Now the court must apply the patent claims to Polymer's strips, called First Choice test strips, to determine whether the First Choice

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strips fall within the scope of the '468 patent claims. See C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 673 (Fed. Cir. 1990). As noted above, if an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. *Graver Tank*, 339 U.S. at 607.

i. Alleged Disputes of Fact

*6 LifeScan alleges that there is no genuine dispute of material fact concerning the features of the First Choice strips and of the strip claimed in the '468 patent. Polymer alleges that disputes of fact preclude summary judgment on the issue of whether each element of the '468 claims is found in the First Choice strips. The court addresses each of Polymer's factual contentions in turn.

First, Polymer argues that there is a dispute of fact as to whether its First Choice strip functions "just as described in the '468 patent." However, in support of its contention that the "First Choice strip in use functions in a substantially different manner from the strip disclosed and claimed in the '468 patent," Polymer simply refers to the declarations of two of its witnesses, an attorney, Gerald Bjorge, and Dr. Callis. This general assertion is insufficient to raise a genuine issue of fact in response to the specific facts submitted in support of LifeScan's motion. In addition, the court has reviewed the cited declarations and finds that they do not support Polymer's assertion of a dispute of fact on this issue, but instead contain disputes as to the legal interpretation of the claim language.

Second, Polymer alleges that there is a dispute of fact as to the pH level of the chemical reagents in its strips. As the court found above, the patent claims a strip with a Ph level of 3.8 to 5. As discussed above, Polymer has disputed the claim interpretation, but has not presented evidence disputing LifeScan's statement that "LifeScan's testing of the First Choice strips indicates that the strips are coated at a Ph within the range." Finally, at oral argument Polymer did not dispute that its own scientist, Dr. Gleisner, indicated during his deposition that Polymer's strips have a pH level of 4.4 when dry. Thus, the pH level of the

First Choice strips falls within the 3.8 to 5 pH range specified in claim 3 of the '468 patent.

Finally, Polymer asserts that there is a factual dispute concerning whether hemoglobin in the red blood cells which is filtered out and held at the surface of the test strip is visible to the optics of the meter apparatus. However, as the court discussed above, the claim is not limited to this interpretation and therefore, Polymer's arguments do not create a material dispute of fact. Rather, Polymer's assertion that its First Choice strip "has substantial free hemoglobin permeating through the porous portion of the strip" places the strip within the claim as interpreted by the court.

Thus, based on the foregoing, the court finds that there is no genuine dispute of material fact precluding summary judgment on the issue of literal infringement of the '468 claims.

ii. Elements of the '468 Patent Claims

LifeScan has presented undisputed evidence that all of the elements of the claims of the '468 patent are found in the First Choice strips made by Polymer. The court has reviewed the evidence submitted by the parties and compared it to the claim language. Each element of the three claims is found in the First Choice strips. The court finds that there is no limitation on the '468 claims requiring the strip to be in place in the blood-glucose monitoring apparatus with a sample of whole blood placed on it. Nor is there a limitation requiring that the "optically visible hemoglobin" be found only in red blood cells held at the surface of the testing strip. Finally, the pH levels of the First Choice strips fall within the range specified in claim 3.

*7 Because each element of the claims of the '468 patent is found in the First Choice strip manufactured and sold by Polymer, the court finds that LifeScan has met its burden on summary judgment. Therefore, LifeScan's motion for summary judgment of literal infringement of the '468 patent is hereby GRANTED.

2. LifeScan's Motion for Summary Judgment of No Implied License Under the '468 Patent

LifeScan sells One Touch meters for home-use

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blood-glucose monitoring and also sells One Touch testing strips for use in taking blood glucose measurements. LifeScan claims patents on the meters *per se*, (U.S. Patent No. 5,059,394); on the strips *per se*, (the '468 patent);^{FN1} and on the methods of making the blood glucose determinations when a testing strip, such as the First Choice or the One Touch strip, is used with a One Touch meter, (the '346 and '487 patents referred to previously in this order). As an affirmative defense to LifeScan's allegations of infringement of the '468 patent, Polymer has asserted that purchasers of LifeScan's One Touch meters are impliedly licensed to use Polymer's First Choice strip and that therefore, Polymer cannot be liable for infringement of the '468 strip patent.

LifeScan moves for summary judgment of no implied license under the '468 patent,^{FN2} asserting that the implied license argument is available to Polymer only if the '468 patent is a method or combination patent, as opposed to a product patent. Therefore, if the court determines, as it has above, that the '468 patent is a product patent, LifeScan argues that Polymer cannot raise the defense of implied license. The court agrees that the implied license doctrine is limited to method or combination patents and notes that Polymer has cited no case to the contrary. However, because Polymer expends great effort arguing that an implied license held by the consumers could create a defense to its own infringement liability, the court addresses the argument below.

a. The Doctrine of Implied License

The doctrine of implied license was described in United States v. Univis Lens Co., 316 U.S. 241, 249-51 (1942). In that case, the patent at issue covered multifocal eyeglass lenses. The patent owner sold blank lenses to its licensees. The Court held that when the licensees purchased the blank lenses, they acquired an implied license to complete the lenses through grinding and polishing, thereby practicing the final stage of the patented process. The Court stated that:

... it is plain that where the sale of the blank is by the patentee or his licensee -- here the Lens Company -- to a finisher, the only use to which it could be put and the only object of the sale is to enable the latter to

grind and polish it for use as a lens by the prospective wearer. An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, and upon familiar principles the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold....

*8 *Id.* at 249 (citations omitted).

The parties in this matter cite two Federal Circuit cases which have also addressed the implied license doctrine, Met-Coil Systems Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686-87 (Fed. Cir. 1986) and Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 925 (Fed. Cir. 1984). In Bandag, the owner of a patent claiming a method for retreading tires, Bandag, Inc., sued Al Bolser Tire Stores, Inc. for infringing its patented method of retreading tires by using Bandag equipment which performed the patented methods. Bolser had purchased the equipment from a terminated Bandag franchisee, but was not licensed by Bandag to use it to perform the patented methods. Bolser argued that because Bandag did not prevent the sale of the equipment to a non-franchisee, and because the equipment would need to be modified in order to be used for a non-infringing purpose, that Bolser had acquired an implied license to use the equipment to practice the patented method. Bandag, 750 F.2d at 906-07, 924. However, the Federal Circuit Court of Appeals rejected those arguments, stating that "no license can be implied, where as here, the equipment involved has other noninfringing uses, even if only as replacement parts," *id.* at 924 (citation omitted), and that "[a] mere sale does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred." *Id.* at 925 (citation omitted).

In the second case cited by the parties, Met-Coil, the Federal Circuit addressed whether "a patent owner's unrestricted sale of a machine useful only in practicing the claimed inventions presumptively carry[ed] with it an implied license under the patent." Met-Coil, 803 F.2d at 685. On the facts of that case, the Federal Circuit court held that the "patent owner's unrestricted sales of a machine useful only in performing the claimed process and producing the claimed

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product 'plainly indicate that the grant of a license should be inferred.'" *Id.* at 687. Therefore, the court held that "[a]bsent any circumstances tending to show the contrary," the sale of the machine gave Met-Coil's customers "an implied license to practice the inventions claimed in Met-Coil's patent." *Id.*

Finally, the burden of proving the existence of an implied license is on the accused infringer. *Id.*

b. Application of the Implied License Doctrine

It is evident that there can be no implied license in this case, even utilizing the analysis in the "method" cases. First, Polymer has failed to show that there are no noninfringing uses for the test strip claimed in the '468 patent.^{FN3} In fact, Polymer itself alleges that its own use of the test strips in setting calibration codes for its strips is a non-infringing use. Second, the circumstances of LifeScan's sale of its meters and test strips do not "plainly indicate that the grant of a license" to Polymer to make and sell the patented test strips "should be inferred." *Bandag*, 750 F.2d at 925. Finally, the court finds that whether or not LifeScan's customers have an implied license to practice the methods claimed in the two method patents, the '346 and '487, such a license does not create an implied license for Polymer to make and sell the test strips claimed in the '468 patent.^{FN4} Polymer's argument that the consumers' alleged right to practice the method patents would be meaningless unless Polymer was granted a corresponding right to make and sell another patented product is frivolous as best.

*9 Therefore, LifeScan's motion for summary judgment of no implied license under the '468 patent is GRANTED.

3. Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Pursuant to 35 U.S.C. Sec. 112

Polymer moves for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112, which provides that the patent specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Sec. 112, Para. 1. Sec. 112 also requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. Sec. 112, Para. 2.

According to the Federal Circuit, the Sec. 112, Paragraph 1 "written description" requirement exists to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the applicant] was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis in original). Sec. 112, Paragraph 2 requires the claims to have a "clear and definite meaning when construed in the light of the complete patent document." *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The test for definiteness under Sec. 112, para. 2 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Compliance with the "written description" requirement of Paragraph 1 of Sec. 112 is a question of fact. *Vas-Cath*, 935 F.2d at 1563. "[T]he description must clearly allow persons of ordinary skill in the art to recognize what is claimed." *Id.*

The presumption of validity of a U.S. patent, established by 35 U.S.C. Sec. 282, "requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence." *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (citing *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984)).

In support of its motion, Polymer has alleged numerous deficiencies in the patent specification, the textual description portion of the patent, and a lack of definiteness in the claims which define the "metes and

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bounds” of the invention. Polymer alleges that the specification does not describe what is meant by the words “in the presence of optically visible hemoglobin;” the specification does not describe that red blood cells from the whole blood sample pass into the pores of the matrix; the specification does not define the term “hematocrit” as meaning “hemoglobin;” as well as other alleged deficiencies in the specification and the claim language.

*10 Polymer has failed to present any evidence on the issue of how one skilled in the art would understand the language of the specification or the claims of the '468 patent. Instead, Polymer relies on its claim that Dr. Smith is not credible and argues that the indefiniteness and lack of clarity in the specification and claim language is clear on the face of the patent and that the court should, as a matter of law, determine that the patent fails to meet the Sec. 112 requirements.

LifeScan has, with the declaration of Dr. John Smith, LifeScan's Vice President of Research and Engineering, presented factual evidence that one skilled in the art would understand the '468 patent specification and that the specification and claim language is sufficiently clear and definite to meet the requirements of Sec. 112. Additionally, LifeScan has presented evidence, through Dr. Smith, that one skilled in the art would understand the metes and bounds of the claims when read in light of the specification. The court finds Polymer's arguments that Dr. Smith is not credible to be insufficient to overcome LifeScan's presentation of genuine disputes of material fact with respect to this motion. Because the court is unable to say, as a matter of law, that the claim and specification language fails to sufficiently describe the invention claimed, Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112 is hereby DENIED.

4. Polymer's Motion for Summary Judgment of Invalidity of the '468 Patent Under 35 U.S.C. Secs. 102(b) and 103

Polymer moves for summary judgment, arguing that the '468 patent is invalid because claims 1 and 2 of the patent are “anticipated,” and claims 2 and 3 are

“obvious,” in light of prior art. As noted above, the presumption of validity of a United States patent, established by 35 U.S.C. Sec. 282, “requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence.” *Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

a. The Law of Anticipation

The law of anticipation is found in 35 U.S.C. Sec. 102(b). Pursuant to that statute, “[a] person shall be entitled to a patent unless ... (b) the invention was patented or described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States,” 35 U.S.C. Sec. 102(b). A patent claim is anticipated “only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros.*, 814 F.2d at 631 (citation omitted).

b. The Law of Obviousness

The law of obviousness is found in 35 U.S.C. Sec. 103, which reads as follows:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

*11 35 U.S.C. Sec. 103. To determine whether an invention would have been obvious at the time it was made, the court must “determine the scope and content of the prior art;” “ascertain the differences between the prior art and the claims at issue;” and “resolve the level of ordinary skill in the pertinent art.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991), (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). In addition, secondary considerations such as “commercial success,” “long felt but unsolved needs,” and “failure of others to invent,” “are also relevant to the obviousness inquiry.” *Ryko*, 950 F.2d at 716, (citing *Graham*, 383 U.S. at 17-18).

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c. Application to the Facts

Polymer alleges that the '468 patent is invalid because each element of claim 1 is anticipated in European patent application no. 0 140 337 by Dappen (the "Dappen" reference) and in European patent application no. 0 110 173 by LifeScan, Inc. (the "EP '173" reference). Polymer also argues that each element of claim 2 of the '468 patent is anticipated by EP '173. Finally, Polymer alleges that claims 2 and 3 would have been obvious; claim 2 from Dappen combined with the teachings of Ngo, et al. (found at 105 Anal. Biochem. 389-97 (1980)) which allegedly makes the dye couple system of the '468 obvious; and claim 3 from the teachings of Dappen combined with Geoghegan, et al. (found at 60 J. Immuno. Methods 61-68 (1983)) which allegedly would have made the pH range of claim 3 obvious.

In response to Polymer's motion, Lifescan has presented numerous issues of disputed fact underlying the determination of whether the '468 patent claims were anticipated or rendered obvious by prior art. In support of its opposition, LifeScan has submitted the declaration of Dr. Smith, who provides evidence of how one skilled in the art would interpret various aspects of the prior art references as well as the '468 patent. Polymer responds that there is not a dispute of material fact because LifeScan's arguments concern irrelevant issues of fact. Polymer additionally asserts that the court should discount Dr. Smith's testimony and therefore LifeScan's reliance on his testimony. The court will not, on summary judgment, determine the issue of credibility of witnesses. Dr. Smith testified that he was not skilled in the art of the legal interpretation of patent claims, as he is "a scientist, not a lawyer." That testimony does not in any way preclude LifeScan's reliance on Dr. Smith for matters beyond "the legal interpretation of patent claims" including how one skilled in the relevant scientific field would understand the prior art references.

Based on the evidence presented by LifeScan and Polymer, the court finds that there exist genuine disputes of material fact concerning what may be anticipated by, and what may be rendered obvious by, the teachings of the prior art references. These include,

but are not limited to, the following: whether one skilled in the art would understand Dappen's "registration layer" to be "porous;" whether the absorbance characteristics of Dappen's dyes are "inherently" those required by the '468 patent claims; whether the greater rate of absorption of light by the Dappen dye system meets the requirement of the '468 patent claims that it not absorb light "to any significant extent at about 700 nm;" whether it is obvious from Dappen or Geoghegan that the dye precursors in Geoghegan should be substituted for those in Dappen; and whether it would be obvious that the appropriate pH level is from 3.8 to 5.

*12 Finally, in addition to the above disputed facts, the court finds that the evidence of so-called "secondary" considerations such as commercial success, long felt but unsolved needs, and failure of others to invent, weighs heavily in favor of LifeScan on the issue of obviousness.

Based on the foregoing, the court concludes that there are genuine disputes of material fact precluding summary judgment on the issues of anticipation and obviousness and therefore Polymer's motion for summary judgment under 35 U.S.C. Secs. 102(b) and 103 is DENIED.

C. The '346 and '487 Patents

The following motions relate to both the '346 and the '487 patents: LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents and Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents.

1. LifeScan's Motion for Summary Judgment of Literal Infringement of the '346 and '487 Patents

LifeScan alleges that Polymer literally infringes various claims of the '346 and '487 patents. By statute, "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a). In addition, "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. Sec. 271(b). Finally, [w]hoever sells a ... material ... for use in practicing a patented process, constituting a material part of the

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invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. Sec. 271(c). LifeScan has the burden of proving infringement by a preponderance of the evidence. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

As set out above in Section II.B.1, to determine whether or not a patent has been literally infringed, the court follows a two-step process. First, the court must ascertain the proper meaning or interpretation of the patent claim itself. Autogiro Co. of Amer. v. U.S., 384 F.2d 391, 401 (Ct. Cl. 1967); see also Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1258 (Fed.Cir. 1989). In construing the claims, the court should consider, if required, the claim language, the other claims, the prior art, the prosecution, and the specification. S.R.I. Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985).

After the court has determined the proper meaning or interpretation of the patent claims themselves, the next step is to apply the claims to the allegedly infringing device to determine whether that device falls within the scope of the claims. C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 673 (Fed. Cir. 1990). If an accused product exhibits features corresponding to each of the elements set forth in any patent claim, then literal infringement exists. Graver Tank, 339 U.S. at 607.

*13 LifeScan alleges that Polymer literally infringes, or induces its customers to infringe, at least claims 1-3, 6-8, and 10-18 of the '346 patent, which are set forth in Appendix A of this order. LifeScan also alleges that Polymer has literally infringed claims 1 and 2 of the '487 patent, which are set forth in Appendix B of this order.

In response to LifeScan's motion, Polymer alleges that there are disputes of fact which preclude summary judgment of literal infringement of the '346 and

'487 patents. However, most of the alleged factual disputes are actually disputes about the legal interpretation of the claim language.

The parties dispute whether Polymer's First Choice strip, and the LifeScan One Touch strip, are composed of single-layer membranes or multi-layered membranes. This court finds that this is not a factual dispute, as the parties agree that the strips are made in the same manner, but rather is a semantic disagreement over the characterization of the resulting strip and the legal meaning of the phrase "single-layer membrane" as used in claims 1, 10 and 15. The strips are created by a technique taught in the patents which consists of "cast[ing] the hydrophilic polymer onto a core of non-woven fibers." The court finds that the resulting membrane, having been cast on a non-woven support, is single-layer. It is undisputed that both strips are formed in this manner. Therefore, the court finds that Polymer's First Choice strips fall within the language of claims 1, 10, and 15.

The parties also dispute the meaning of the phrases "filters out red blood cells" and "exclude red blood cells" found in claims 1, 10, and 15. The court finds that the phrases, properly interpreted, do not require the porous membrane to prevent absolutely all red blood cells from entering the membrane. It is undisputed that both strips do "filter[] out" and "exclude" red blood cells.

The remaining issues raised by Polymer in its opposition to LifeScan's motion of literal infringement all purport to be factual disputes. However, the court has reviewed Polymer's statement of disputed facts and finds that all but two of the issues raised by Polymer are legal arguments as to the meaning of the claims or semantic disputes concerning the description of First Choice strips, which do not actually raise any factual issues themselves. The two exceptions are Polymer's statement that the dye product in the First Choice strips absorbs light at the same wavelength that red blood cells absorb light and Polymer's contention that its use of the strips does not involve the practice of the patented methods. However, as to the issue of the rate of light absorption, Polymer's only attempt to create a genuine factual dispute has been to present unsubstantiated affidavit evidence which

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contradicts the prior sworn testimony of another of Polymer's own witnesses on this issue, without any explanation of the discrepancy. At oral argument, Polymer's counsel did not deny that its expert Dr. Callis had previously testified that the dye product *does* absorb light at a different wavelength than does red blood cells, nor did Polymer's counsel contend that Dr. Callis had been mistaken when he testified concerning his conclusions after conducting a scientific examination. The court finds that Polymer has failed to create a genuine factual dispute on this issue.

***14** As to the second allegedly disputed factual issue, concerning Polymer's use of the strips in a manner which actually practices the patented methods, the court finds that Polymer has failed to rebut the factual assertions by LifeScan that Polymer's use of the meters, whether to demonstrate them, or for clinical testing, would constitute practice of the claimed methods. At oral argument, Polymer's counsel failed to deny that Polymer has used the meters to practice the claimed methods. Instead, in Polymer's statement of disputed facts, Polymer focuses on arguing that using the meters to set calibration codes for its strips would not be an infringing use because the meter is not being used to test the amount of glucose, which is already known during the procedure. Whether or not the use of the meter to set the calibration code on the strips constitutes practicing the claimed patented methods, Polymer notably fails to deny that it has used the meters to measure glucose.

Finally, Polymer questions whether LifeScan has presented sufficient evidence showing that the meter, when used, actually practices the claimed methods. The court finds that, through Dr. Smith's testimony, LifeScan has put forth sufficient evidence that use of the meters to measure blood glucose does practice the claimed methods and therefore Polymer must come forth with counterevidence demonstrating that there are genuine issues of material fact on the issue. See Scripps Clinic & Res. Fdn. v. Genentech, Inc., 927 F.2d 1565, 1571 (Fed. Cir. 1991) (citations omitted). Polymer has not done so. Therefore, the court finds that there is no genuine dispute of material fact concerning whether the meter actually practices the claimed methods, and therefore whether Polymer's

use of it thereby infringes the method patents.

In addition, Polymer has failed to rebut the evidence offered by LifeScan that use of the First Choice strips in the meters, when measuring blood glucose levels, infringes claims 1-3, 6-8, and 10-18 of the '346 patent and claims 1 and 2 of the '487 patent, as those claims have been interpreted by the court. Based on this analysis, the court GRANTS LifeScan's motion for summary judgment of literal infringement of claims 1-3, 6-8, and 10-18 of the '346 patent and claims 1 and 2 of the '487 patent.

The court notes that Polymer has again raised the possibility that the customers purchasing the First Choice strips may have an implied license to practice the methods claimed. However, at this stage, the court is merely determining infringement by Polymer of the claimed methods, not any possible defenses to that infringement. The court has, in this order, denied summary judgment to Polymer on the issue of whether the consumer purchasers of the One Touch meters have been granted an unrestricted implied license to practice the claimed methods because disputed factual issues exist.

2. Polymer's Motion for Summary Judgment of Non-Infringement of the '346 and '487 Patents

***15** Polymer has moved for summary judgment of non-infringement of the '346 and '487 method patents on the basis of the following argument: only the consumer users of the One Touch meters can directly infringe the method patents (the '346 and the '487) because only they practice the claimed methods; the consumers have an implied license to use the meters in their intended fashion; consumers additionally are impliedly licensed to use the meters with First Choice test strips because either the consumer bought a meter without a sticker cautioning the buyer about patent infringement or because the consumer purchased a meter *with* a warning sticker but the stickers are ineffective as a matter of law. Polymer additionally argues that because the consumers are allegedly impliedly licensed to use the meters with First Choice strips, there is no *direct* infringement and therefore Polymer cannot be derivatively liable for inducing or contributory infringement. Finally, Polymer claims it

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does not practice the method patents itself, and therefore cannot be directly liable for infringement of the method patents.

As set out in detail above, in section II.B.2. of this order, an implied license will only be found when there is no non-infringing use for the article sold (i.e., the only use for the article is one that carries out a patented method or completes a patented combination) and the circumstances of the sale plainly indicate that the grant of a license should be inferred. Met-Coil Systems Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686-87 (Fed. Cir. 1986); Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 925 (Fed. Cir. 1984). The burden of proving the existence of an implied license is on the accused infringer. Met-Coil, 803 F.2d at 687.

The court cannot grant summary judgment on this motion. LifeScan has presented evidence creating a genuine dispute of fact concerning whether there are non-infringing uses for the One Touch meters. Under Bandag, an implied license does not exist if there are non-infringing uses. Bandag, 750 F.2d at 924 ("no license can be implied, where as here, the equipment involved has other noninfringing uses, even if only as replacement parts").

In addition, even if there were no disputes of fact on the issue of non-infringing uses, this court cannot say as a matter of law, on the evidence presented by Polymer, that the circumstances of the sales "plainly indicate that the grant of a license should be inferred." Met-Coil, 803 F.2d at 687. The '346 patent issued in June, 1990 and the '487 patent in September, 1991. LifeScan's '468 patent was issued on April 19, 1994. Under United States patent law, a patent owner has no enforceable rights under a patent until the patent issues. Marsh v. Nichols, Shephard & Co., 128 U.S. 605, 612 (1888). LifeScan has presented a genuine issue of material fact as to what expectation customers could have had concerning a license to use a then non-existent patent. Additionally, Polymer has brought forward no evidence of the grant of such an implied license except for the actual sales of the meters, some sold with and some without caution stickers. Notably, no test strips other than LifeScan's strips were authorized by the FDA to be marketed for

use with the One Touch meter at that time. Additionally, LifeScan has presented evidence of customer literature included in its meter packaging which creates a factual issue concerning the circumstances surrounding the sales of the meters.

*16 With respect to meters sold at later dates, LifeScan has similarly raised genuine disputes of material fact. No strips other than LifeScan's own strips were available for use with One Touch meters prior to the time at which LifeScan began placing stickers cautioning purchasers about patent infringement possibilities. In addition, LifeScan continued placing information in its packaging which creates a dispute of fact concerning the circumstances of the sales and is evidence precluding a finding of an implied license. Finally, Polymer has failed to convince the court that the caution sticker placed on the LifeScan One Touch meters beginning in April, 1993 is ineffectual, as a matter of law, to restrict the use of the meter. At the very least, the sticker language creates a dispute of fact concerning the expectations of a reasonable customer and whether the circumstances of the sales "plainly indicate that the grant of a license should be inferred." Met-Coil, 803 F.2d at 687.

Because this court finds that LifeScan has raised genuine disputed issues of material fact in opposition to the motion, Polymer's motion for summary judgment of non-infringement of the '346 and '487 patents is DENIED.

D. LifeScan's Motion for Summary Judgment of No Misuse with Respect to All Three Patents

LifeScan has moved for summary judgment on the issue of whether or not there was misuse of the three patents at issue in this case, the '468, the '346 and the '487. Polymer has asserted misuse of the patents as a defense to liability. Patent misuse as a defense refers to inequitable conduct engaged in by the patent owner which renders the patent unenforceable. Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 493-94 (1942). 35 U.S.C. Sec. 271(d), enacted in 1952, codified the doctrine of contributory infringement and addressed the issue of patent misuse as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent

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shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

- (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;
- (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;
- (3) sought to enforce his patent rights against infringement or contributory infringement.

35 U.S.C. Sec. 271(d).

The Supreme Court interpreted Sec. 271(d) in Dawson v. Rohm & Haas Co., 448 U.S. 176 (1980). In Dawson the court held that "the provisions of Sec. 271(d) effectively confer upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods. A patentee may sell a nonstaple article himself while enjoining others from marketing the same good without his authorization." *Id.* at 201. A nonstaple article is "one which was designed to carry out the patented process and has little or no utility outside of the patented process." Polysius Corp. v. Fuller Co., 709 F.Supp. 560, 576 (E.D. Pa. 1989). Polymer has presented no evidence disputing LifeScan's claim that the test strips designed for use with LifeScan's One Touch meters are nonstaple items.^{FN5} The court finds that the blood glucose test strips are nonstaple items.

*17 The court notes that in Dawson the patentee was permitted to limit competition in the sale of an *unpatented* staple item, whereas here the strip itself is patented, thus making this an even stronger case in favor of a finding of no misuse.

The court is not persuaded by Polymer's arguments that the holding in Dawson has been restricted by the enactment of the Patent Misuse Reform Act of 1988, codified at 35 U.S.C. Secs. 271(d)(4)(5).^{FN6} It is clear from the legislative history that Congress intended to extend, not limit, the protection provided by Dawson. See 134 Cong.Rec. S17146-48 (Oct. 21, 1988) (Amendments enacted to "support [the] enhancement of intellectual property rights" and to

"deter misuse claims that unnecessarily burden infringement litigation"). Since the 1988 amendments courts have continued to interpret Dawson as this court does here. See e.g., Joy Technologies Inc. v. Flakt, Inc., 1992 WL 188814, *2, 1992 U.S. Dist. LEXIS 21720, *8, 24 U.S.P.Q.2d 1150, 1152 (D.Del. 1992), *vacated and remanded on other grounds*, 6 F.3d 770 (Fed. Cir. 1993); Alcon Laboratories Inc. v. Allergan Inc., 1990 WL 267418, *14, 1990 U.S. Dist. LEXIS 13348, *43-44, 17 U.S.P.Q.2d 1365, 1377 (N.D. Tex. 1990); Polysius, 709 F.Supp. at 576.

As the court has found that blood glucose test strips are nonstaple items, the court holds that LifeScan has not misused the patents at issue. Therefore, the court hereby GRANTS LifeScan's motion for summary judgment of no misuse of the '468, the '346 and the '487 patents.

E. Polymer's Motion to Amend Answers

Pursuant to Fed.R.Civ.P. 15(a) Polymer has moved to amend its answers to the complaints filed in this matter.^{FN7} Polymer requests leave to amend its answers in order to add specific allegations of inequitable conduct pleaded as an affirmative defense in this case.

Whether to permit a party to amend its pleading is a matter within the court's discretion. Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 330 (1971). The court should consider whether allowing the proposed amendment will cause undue delay, whether it is in good faith, whether it will unduly prejudice the opposing party and whether the amendment may be futile. Foman v. Davis, 371 U.S. 178, 182 (1962).

The court has considered the proposed amendments and has determined that if allowed, undue delay would result. The court is convinced that if amendment were permitted, the court would need to allow LifeScan additional discovery. The discovery period in this case had passed prior to Polymer's filing of its motion to amend.^{FN8} Extensive discovery has already occurred and any further discovery permitted now would jeopardize the current trial date of January 30, 1995. In addition, the court believes that the

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amendments would cause the trial to be longer than the currently scheduled fifteen-day jury trial, which would cause additional scheduling difficulties, thus delaying the eventual resolution of the entire case. The court also finds that LifeScan would be unduly prejudiced if it were required to interrupt its trial preparation to undertake discovery and/or file motions concerning the proposed amendments. The court notes that the October 13, 1994 deadline for filing dispositive motions passed the same day this motion was filed.

*18 LifeScan argues that Polymer's proposed amendments would also be futile and would not withstand a motion to dismiss. The court has not determined whether or not the amendments would be futile. The trial date in this matter is rapidly approaching and the court does not wish to divert the parties from their trial preparation by requiring an additional round of briefing on the legal sufficiency of the amendments. Finally, the court believes it would be improper to delay the trial in this matter any longer.

F. LifeScan's Motion for Preliminary Injunction

In this motion, LifeScan requests that Polymer be preliminarily enjoined from "manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters, and any other product which infringes LifeScan's United States Letters Patent No. 5,304,468." ^{FN9}

1. Legal Standard

Injunctive relief in patent cases is authorized pursuant to 35 U.S.C. Sec. 283 and under case law. *See e.g., Smith Int'l., Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-79 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 996 (1983). The Federal Circuit has established the following test for determining whether to issue an injunction in patent matters:

... to obtain a preliminary injunction, pursuant to 35 U.S.C. Sec. 283, a party must establish a right thereto in light of four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest.

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

2. Discussion

Above, the court has determined that the '468 patent claims the blood glucose test strips themselves, and thus is a product patent, rather than a patent for a method or combination of method and product. The court also determined that Polymer has literally infringed the '468 patent and that LifeScan has not impliedly licensed Polymer under the '468 patent to make, use, or sell the blood glucose test strips. Additionally, the court found that LifeScan has not misused the '468 patent. Finally, the court found that it could not say, as a matter of law, that the '468 patent was invalid pursuant to 35 U.S.C. Sec. 112, for indefiniteness, or pursuant to 35 U.S.C. Secs. 102(b) and 103, for anticipation and obviousness.

a. Reasonable Likelihood of Success on the Merits

According to the Federal Circuit, in order to merit the granting of a preliminary injunction, "a patent holder must establish a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hybritech*, 849 F.2d at 1451. As noted, the court has determined, as a matter of law, that Polymer has literally infringed the '468 patent. The court has also determined that LifeScan has not misused the '468 patent, or impliedly licensed Polymer to make, use or sell the blood glucose test strips claimed by the '468 patent. Accordingly, Polymer cannot assert those issues as defenses at trial. However, because the court has not determined whether or not the '468 is valid as a matter of law, ^{FN10} it remains for the court to consider the likelihood that LifeScan will prevail at trial on the validity issue.

*19 The court has considered the various prior art references cited by Polymer in connection with Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b)

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and 103. Having considered this evidence, the court finds that there is a substantial likelihood that LifeScan will demonstrate at trial that the '468 patent claims are not disclosed in the prior art, and are not rendered obvious or anticipated by the prior art references. The court will not be the ultimate finder of fact on that issue; it will remain for the jury to determine. However, for purposes of the motion for a preliminary injunction, the court must weigh the evidence and thus it has considered whether the claims in the '468 patent would have been anticipated or obvious from the prior art references and concludes that LifeScan has made a strong showing that it will prevail on the issue.

Specifically, the court finds that the following differences alleged by LifeScan are likely to be persuasive to the jury on the issue of whether the strip is novel: most of the prior art relied upon by Polymer was considered by the Patent Examiner prior to his allowance of the '468 patent claims, in particular the court believes that there is persuasive evidence that the European Patent Application No. 0110173A ("the '173 patent") was considered by the Patent Examiner and found not to preclude the '468 claims; the court also finds that LifeScan has presented compelling evidence that the '173 patent does not disclose both a "sample receiving surface" and a "testing surface" and that the Przybylowicz and Clement patents concern "multi-layer strips" unlike the '468 single-layer strip; the Przybylowicz and Clement patents do not disclose a reading taken "in the presence of optically visible hemoglobin;" the Dappen reference does not appear to the court to disclose a porous portion as required by the '468 patent; the Dappen reference dye system does not appear to meet the '468 claim requirement that it not absorb light to any significant extent at about 700 nm; it does not appear that Dappen or Geoghegan teach that the dye precursors in Geoghegan should be substituted for those in Dappen; it does not seem that the references cited by Polymer would make it obvious that the appropriate pH level is from 3.8 to 5, as required by claim 3 in the '468 patent. Thus, based on the court's view of the prior art evidence, LifeScan is likely to prevail on the issues of obviousness and anticipation.

In addition to the above findings concerning the prior

art references, the court finds that LifeScan has made a showing of likelihood of success on the issue of validity by presenting considerable objective evidence of non-obviousness of the inventions claimed in the '468 patent. Specifically, the court finds that LifeScan has made a strong showing of the following evidence of non-obviousness: the inventions claimed in the '468 strip patent have enjoyed considerable commercial success; Polymer has experienced tremendous growth in sales of its One Touch strips which the court has found above infringe the '468 claims; the improvement in results for the users of the glucose monitoring system which was achieved with non-wipe strips is marked and has contributed to the commercial success; and finally, LifeScan has presented considerable evidence that Polymer developed its First Choice strips by following the '468 patent claims and disclosure. Based on the objective evidence presented by LifeScan on the issue of non-obviousness, the court finds that LifeScan has made a strong showing that it is likely to succeed on the issue of obviousness at trial.

*20 Finally, the court finds that LifeScan is likely to prevail at trial on the issue of validity under 35 U.S.C. Sec. 112, which requires definiteness in the claim and specification language. Although the court found above that there remained disputed issues of fact, the court has considered the evidence presented by both sides on the issue and is of the opinion that LifeScan is more likely to prevail on the issue of whether, through the testimony of Dr. Smith, the '468 description would allow one skilled in the art to recognize what is claimed.

Therefore, the court finds that LifeScan has shown a likelihood of success on the merits of the issue of validity. As the court has already found that Polymer has infringed the '468 patent as a matter of law, LifeScan has "establish[ed] a likelihood of success on the merits both with respect to validity of its patent and with respect to infringement of its patent." *Hy-britech*, 849 F.2d at 1451.

b. Irreparable Harm

The court makes the following findings with respect to the issue of irreparable harm: LifeScan did not

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delay in seeking a preliminary injunction with respect to the infringement of the '468 patent as it filed its preliminary injunction motion (in an action in the Eastern District of Pennsylvania) on the *same day the '468 patent issued*, April 19, 1994; LifeScan's grant of a license to Can Am, another strip manufacturer, does not negate the possibility of irreparable harm caused by Polymer's actions; Polymer's sales have increased dramatically over the past eight months; Polymer has captured a substantial portion of the market in test strips over the past months; LifeScan is losing market share to Polymer; Polymer's assets are insufficient, based upon the testimony of Polymer's chief financial officer Ms. Helenick, to satisfy the damages LifeScan will be able to claim if it prevails on the merits at trial; and LifeScan is likely to lose good will with its customers because of the pricing difference between One Touch and First Choice strips. Therefore, based on these findings, the court holds that LifeScan has demonstrated that it will suffer irreparable harm if Polymer is not enjoined.

c. The Balance of Hardships

The court finds that the balance of hardships tips in favor of LifeScan. LifeScan cannot recover from the irreparable harm outlined above even if it prevails at trial. Additionally, LifeScan has offered to post a bond sufficient to cover any potential damages suffered by Polymer due to an injunction. Although the court recognizes that Polymer and its employees will be harmed substantially by an injunction, it is persuaded that such harm is less than that which would be suffered by LifeScan if Polymer continued producing and selling the First Choice strips.

d. Impact on the Public Interest

The court finds that although there are advantages to the public in being able to purchase low-cost medical products, the public interest favors the granting of an injunction in favor of LifeScan. Congress has determined that "it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the 'useful arts' to expend the time and money necessary to research and develop new products." *Eli Lilly & Co. v. Premo Pharmaceutical Labs., Inc.*, 630 F.2d 120, 137 (3d Cir.), cert. denied, 449 U.S. 1014

(1980) (citations omitted). Congress has made the legislative determination that it is not in the public interest to permit the infringement of those temporary monopolies as it undermines inventor incentive.

e. Conclusion

*21 Having balanced the relevant factors, and having considered all of the evidence presented by the parties, the court finds that LifeScan has demonstrated that it is entitled to a preliminary injunction prohibiting Polymer from manufacturing, using, or selling, or inducing others to manufacture, use, or sell, blood glucose test strips, including the First Choice test strips, for use with One Touch meters. For security, pursuant to Fed.R.Civ.P. 65, LifeScan shall file with the Clerk of this court a surety bond in the amount of \$5,000,000. within five working days of this order.

III. CONCLUSION

Based on the foregoing, the court hereby rules as follows:

- 1) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '468 patent;
- 2) the court GRANTS LifeScan's motion for summary judgment of no implied license under the '468 patent;
- 3) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Sec. 112;
- 4) the court DENIES Polymer's motion for summary judgment of invalidity of the '468 patent pursuant to 35 U.S.C. Secs. 102(b) and 103;
- 5) the court GRANTS LifeScan's motion for summary judgment of literal infringement of the '346 and '487 patents;
- 6) the court DENIES Polymer's motion for summary judgment of noninfringement of the '346 and the '487 patents;
- 7) the court GRANTS LifeScan's motion for sum-

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mary judgment of no misuse of the '468 patent, the '346 patent, and the '487 patent;

8) the court DENIES Polymer's motion to amend its answers; and

9) the court GRANTS LifeScan's motion for a preliminary injunction concerning the '468 patent.

APPENDIX A

'346 Patent Claims 1-3, 6-8, and 10-18

1. In a method for determining glucose in a blood sample employing a membrane and a signal-producing system which reacts with glucose to produce a light-absorptive dye product, said system being bound to the membrane, and in which the amount of said dye product is determined by means of a reflectance measurement from a surface of said membrane, an improvement which comprises:

applying an unmeasured whole blood sample to a first surface of a single-layer, substantially reflective, porous, hydrophilic membrane having pores of a size sufficient to exclude red blood cells and which contains said signal-producing system;

making said reflectance measurement on a second surface of said membrane other than the surface to which said sample is applied without removing excess sample or red blood cells from said first surface; and

determining the concentration of glucose in said sample from said reflectance measurement.

2. A method according to claim 1, wherein said signal-producing system produces a dye product which absorbs light at a wavelength different from a wavelength at which said red blood cells absorb and said reflectance measurement is made at two different wavelengths, one absorption wavelength reflectance measurement to correct for background absorbance due to red blood cells and the other reflectance measurement at the absorption wavelength of said dye product.

*22 3. A method according to claim 2, wherein said two wavelengths are at about 635 and 700 nm.

6. A method according to claim 1 wherein said membrane comprises polyamide and said signal producing system comprises glucose oxidase, peroxidase, and

3-methyl-2-benzothiazolinone hydrazone/
3-(dimethylamino) benzoic acid.

7. The method of claim 1, wherein said pores have an average diameter of from about 0.1 to about 3.0 mm.

8. The method of claim 1, wherein said membrane consists essentially of polyamide and has a thickness of from about 0.01 to about 0.5 mm.

10. A method for determining glucose comprising the sequential steps of:

(a) applying a whole blood sample to an application site on a reagent element wherein said reagent element comprises a single-layer, substantially reflective, porous, hydrophilic matrix which filters out red blood cells and to which is bound a signal-producing system comprising glucose oxidase, peroxidase, and a dye indicator, which signal-producing system reacts with glucose to form a reaction dye product;

(b) allowing the sample to migrate to a reading site on said membrane different from said application site;

(c) monitoring reflectance at said reading site for a decrease in reflectance indicative of sample presence in said reading site in order to initiate timing of an incubation period;

and

(d) determining the change in reflectance at said reading site during the incubation period as a measure of dye product formed to determine the amount of glucose in said sample

wherein

all reflectance measurements at said reading site are performed without removing excess sample or red blood cells from said application site and at least one measurement is taken at a wavelength at which light is absorbed by said dye product.

11. A method according to claim 10, wherein said dye indicator is 3-methyl-2-benzothiazolinonehydrazone/3-(dimethylamino) benzoic acid.

12. A method according to claim 10, wherein said hydrophilic membrane comprises a polyamide.

13. A method according to claim 12, wherein said hydrophilic membrane is positively charged.

14. The method of claim 10, wherein said determination of the amount of glucose in said sample further includes determining the change in reflectance at a second wavelength to provide a correction for back-

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ground absorbance at the dye product absorbing wavelength due to an interfering substance in said sample.

15. A method of determining analyte concentration in a liquid, which comprises:

quantitatively measuring baseline reflectance from a first surface of a reagent element comprising an inert, porous, hydrophilic, substantially reflective, single-layer matrix having pores of a size sufficient to exclude red blood cells and a reagent system which interacts with said analyte to produce a light-absorbing reaction product, said reagent system being impregnated in the pores of said matrix, prior to application of said liquid to said reagent element;

*23 applying said liquid to a second surface of said reagent element and allowing said liquid to migrate from said second surface to said first surface;

quantitatively measuring reaction reflectance from said first surface of said reagent element without removing excess sample or non-migrating components of said sample from said second surface;

quantitatively measuring reflectance of interfering substances from said first surface of said reagent element using a wavelength of light reflected by interfering substances and different from the wavelength of light used to measure said reaction product reflectance in order to correct for background reflectance at the reaction product wavelength caused by interfering substances; and

calculating a value expressing said analyte concentration from said reflectance measurements.

16. The method of claim 15, wherein said matrix comprises a polyamide.

17. The method of claim 15, wherein the average diameter of the pores in said matrix is from 0.2 to 1.0 mm and said liquid is whole blood.

18. The method of claim 17, wherein said analyte is glucose, and said reagent produces a light-absorbing reaction product upon reacting with glucose.

FN1. The court has determined above that the '468 patent refers to the "reagent test strip" itself and is not a method or combination patent.

FN2. Lifescan's motion for summary judgment of no implied license is directed to the

'468 patent only. The issue of implied license with respect to the method patents, '346 and '487, is addressed in the motion by Polymer concerning non-infringement of the two method patents.

FN3. Polymer argues that there are no *substantial* noninfringing uses for the strip other than to practice the method patents. LifeScan argues that the standard is whether there are *any* noninfringing uses and alleges that there are indeed noninfringing uses for the meters, including using the meter to measure glucose in substances other than blood.

FN4. LifeScan alleges infringement of the '468 patent not simply due to the use of the test strip by the consumer meter-users, but due to Polymer's activities, pursuant to 35 U.S.C. Sec. 271(a) which states that "[e]xcept as otherwise provided in this title, whoever without authority *makes, uses or sells* any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. Sec. 271(a) (emphasis added).

FN5. Polymer's claims that the meter purchasers are impliedly licensed to use other brands of strips does not create a substantial non-infringing use, rather it would provide the infringing consumer with an implied license defense to infringement liability. *See generally, Dawson*, 448 U.S. 176 (1980).

FN6. 35 U.S.C. Secs. 271(d)(4) and (5) read as follows:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

... (4) refused to license or use any rights to the patent; or

(5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in

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another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or the patented product on which the license or sale is conditioned.

FN7. This matter results from the consolidation of two complaints. Polymer has filed two answers, one to each of the complaints.

FN8. The discovery period in this matter ended on October 4, 1994. Polymer filed the motion to amend its answers on October 13, 1994.

FN9. This motion comes before the court on remand from the Federal Circuit. The Federal Circuit vacated this court's June 9, 1994 order denying LifeScan's motion for a preliminary injunction. *See LifeScan v. Polymer*, Docket No. 94-1369 (Fed. Cir. Oct. 18, 1994). Because the initial order has been vacated, the court intends for this order to supersede the June 9, 1994 order.

FN10. Finding the existence of genuine disputes of material fact, the court has denied Polymer's two motions for summary judgment of invalidity of the '468 patent.

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EXHIBIT D

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Holman v. IMC Mortg. Co.

D.Md.,2001.

Only the Westlaw citation is currently available.

United States District Court, D. Maryland.

Brian HOLMAN, et al., Plaintiffs,

v.

IMC MORTGAGE COMPANY, et al., Defendants.

No. Civ. JFM 99-1778.

Jan. 9, 2001.

*MEMORANDUM*MOTZ, J.

*1 On June 30, 1997 Brian Holman ("Holman") and Richard Toomey ("Toomey") entered into an agreement with IMC Mortgage Co. ("IMC") to sell the assets of their company, Central Money Mortgage Co., Inc. ("CMM"). The Asset Purchase Agreement ("APA") resulted from lengthy negotiations between Holman and Toomey and IMC representatives, in particular Mitchell Legler ("Legler"), who was IMC general counsel and one of its directors. Under the terms of the APA, IMC would pay Holman and Toomey a base payment equal to \$11 million and a contingent payment calculated according to CMM's financial condition and future earnings. IMC would pay the base payment by issuing \$11 million worth of stock to Holman and Toomey. The APA determined the number of shares by dividing \$11 million by the stock's average closing price during the last 10 days of June 1997 ("Average Quoted Price" or "AQP"), which equaled 640,933 shares. To enable Holman and Toomey to convert some of these securities into cash, IMC and the plaintiffs entered into another agreement, the Registration Rights Agreement ("RRA"), which required IMC to register a number of shares with the Securities and Exchange Commission ("SEC"). The RRA calculated this subset of shares by dividing \$5.4 million (roughly half the total base payment) by the AQP. Under this formula, IMC agreed to register 314,640 of the 640,933 base payment shares within 20 days of the closing. The remaining shares could not be sold without meeting an exemption to the SEC rules governing restricted securities.

IMC also entered into employment agreements with Holman and Toomey. Under the terms of the identical agreements, Holman became the President of CMM (now an IMC affiliate) and Toomey served as Vice-President. The agreement provided five-year terms and base salaries for Holman and Toomey of \$300,000 per year with annual cost of living adjustments. Although either party could terminate the agreement, if IMC did not terminate Holman or Toomey for cause, it was obligated to pay the respective employee the remaining salary through the term.

The parties closed the transaction on August 19, 1997 but IMC failed to register the shares within 20 days of closing. Accordingly to IMC, its securities counsel advised it that registering the shares would undermine a potential IMC debt offering; the debt offering subsequently fell through. In January and February of 1998 the parties discussed alternative ways to give Holman and Toomey the benefit of their bargain. Under SEC rules, as of August 19, 1998, all the shares transferred to Holman and Toomey would be alienable. IMC proposed that on August 19, 1998, if the value of the nonregistered 314,640 shares did not equal \$5.4 million, they would "top off" the plaintiffs with sufficient "saleable" shares so that their shares would equal \$5.4 million.

On August 19th and 20th, 1998, Legler and Stuart Marvin ("Marvin"), IMC's Chief Financial Officer, drafted documents affecting this proposal. Because the August 19, 1998 share price was less than the AQP, Legler prepared documents transferring to the plaintiffs an additional 96,790 shares in order to give the plaintiffs value of \$5.4 million. The necessary documents did not reach the plaintiffs until August 24, 1998. Between August 19th and 24th, the share price dropped from \$12.56 to \$10.50. The plaintiffs did not sell their shares; they claim that Legler failed to issue a required opinion letter. They claim Legler's inaction also prevented them from selling the 326,293 shares constituting the remainder of the base payment. By October 1998, the shares were selling for less than \$2.

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*2 The plaintiffs filed suit against IMC and Legler on June 17, 1999. They claimed that Legler and IMC fraudulently induced them into entering the APA by promising to register the 314,640 shares. On August 13, 1999 IMC terminated their employment. The plaintiffs subsequently amended their complaint to include claims for breach of the APA and RRA, negligence and breach of the employment contracts.

The plaintiffs move for summary judgment on counts IV and V for breach of the APA (and RRA), and counts VII and VIII for breach of the employment contracts. IMC and Legler move for summary judgment on counts I, II and III for fraud; IMC also moves for summary judgment on counts VII and VIII for breach of the employment contract.^{FN1} The plaintiffs have filed a Motion to Amend the Amended Complaint to include a claim for fraud based on Legler's representations after September 9, 1997. I will address the counts in order.

^{FN1} Neither party addresses count VI for negligence.

I.

In counts I-III, the plaintiffs assert claims against Legler and IMC for fraud under Maryland common law, 15 U.S.C. § 78j ("Section 10(b)" and "Rule 10(b)-5") and Md.Code Ann. Corps. & Ass'ns § 11-703 (1999). To succeed on any of these claims, the plaintiffs must show, *inter alia*, that Legler intended to deceive them by misrepresenting a material fact.^{FN2} *Gross v. Sussex, Inc.*, 630 A.2d 1156, 1161 (Md.1993) (to recover for common law fraud, a plaintiff must prove, *inter alia*, a false representation for the purpose of defrauding the plaintiff); *Cooke v. Manufactured Homes, Inc.*, 998 F.2d 1256, 1260-61 (4th Cir.1993) (to recover under Section 10(b) and Rule 10(b)-5, a plaintiff must prove, *inter alia*, that the defendant made a false representation or omission of material fact with scienter). The plaintiffs claim that Legler represented that IMC would register the relevant securities within twenty days of closing, enabling Holman and Toomey to sell them. Neither party disputes that IMC did not register the securities within 20 days. An unfulfilled promise may serve as the basis for a fraud claim if the defendant did not have a

present intention to perform it. *Tufts v. Poore*, 147 A.2d 717, 723 (Md.1959) (noting that Maryland recognizes claim based on fraudulent promise); *Alleco Inc. v. Harry & Jeanette Weinberg Found.*, 665 A.2d 1038, 1048 (Md.1995) (same); *Pross v. Katz*, 784 F.2d 455, 457 (2d Cir.1986) ("Making a specific promise to perform a particular act in the future while secretly intending not to perform may violate Section 10(b) ... if the promise is part of the consideration for a sale of securities"); *Burns v. Paddock*, 503 F.2d 18, 23 (7th Cir.1974) ("Where a promise is made with the intention of not keeping it, there is a scheme or artifice to defraud" under Section 10(b)).

^{FN2} There is little state case law applying section 11-703. Although the statutory text differs from Section 10(b), the plaintiffs have not argued that the state statute offers broader protection than its federal counterpart, nor have the defendants argued that it offers narrower protection. Accordingly, I will assume that if the plaintiffs cannot prevail under Section 10(b), they cannot prevail under section 11-703, and vice versa. *Cf. O'Neil v. Marriot Corp.*, 538 F.Supp. 1026, 1032 (D.Md.1982) ("In light of the identity of statutory terms and in the absence of state law to the contrary, the reasonable conclusion is that the Maryland courts would not find a cause of action under state law when there is none under federal law").

I find that the plaintiffs have not produced direct evidence of fraudulent intent and that a jury could not infer intent from other facts. Fraudulent intent can be inferred from the situation of the parties, the activity of the promisor in procuring a transaction, the length of time between the promise and the failure to perform and the defendant's subsequent conduct. *Tufts*, 147 A.2d at 722. Although the short time span between closing and IMC's failure to register the stock may militate in favor of an inference of fraud, IMC has offered evidence indicating that it started the registration process but then changed its position. Marvin states that shortly after the closing he directed Ashley Roberts-Ise, an in-house lawyer, to draft an S-3 registration short form. Marvin Dep. at 70-75; Roberts-Ise Dep. at 21. He reviewed a draft of the

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document at the end of August. Marvin Dep. at 72-73. On September 5, 1997, Ise sent the draft via overnight mail to Peter Kolevzon, the New York lawyer in charge of reviewing securities documentation. Ise Dep. at 22-23. Kolevzon reviewed the document on September 7th. Kolevzon Dep. at 155-56.

*3 But at a meeting in Tampa on September 8th or 9th, IMC executives discussed a debt offering. Legler Dep. at 115-16. At a break in the meeting, Kolevzon advised IMC personnel that registering the plaintiffs' stock would undermine the offering. Kolevzon Dep. at 13, 30-34; Marvin Dep. at 80-83. Kolevzon explained that IMC could not give accurate disclosures in a stock registration prospectus until it finalized the debt covenants. Kolevzon Dep. at 33-34; Marvin Dep. at 80-88. He also explained that disclosing a potential debt offering in the stock registration would raise "gun jumping" concerns with regard to the bond offering itself. Kolevzon Dep. at 32-33. Accordingly, Kolevzon advised Legler and other company officers to delay registration pending completion of the debt offering. Kolevzon Dep. at 13-14, 34-35.

The plaintiffs have provided no evidence disputing this chain of events. Holman states that his primary reason for believing IMC committed fraud was the fact that it never registered the stock.^{FN3} Holman Dep. at 145. Fraudulent intent not to perform cannot be inferred "from the failure to perform the promise alone." *Tufts*, 147 A.2d at 722. Accordingly, I grant summary judgment to IMC and Legler on the first three claims because the plaintiffs have not created a triable issue that IMC promised to register securities when it did not intend to do so.

^{FN3}. I grant the plaintiffs' Motion for Leave to File Declarations. I have reviewed the declarations, but I do not believe that this evidence changes the outcome. These documents do not create a dispute as to whether Legler and IMC had a *present* intention not to register shares when they represented that they would.

II.

The plaintiffs move for summary judgment as to the

breach of contract claims in counts IV and V. In count IV, they allege that IMC breached the APA (and the RRA) by failing to register 314,640 shares within 20 days of closing. In count V, they allege that IMC breached the APA by failing to issue an opinion letter allowing the plaintiffs to sell all of their shares on the one-year anniversary of closing.^{FN4}

^{FN4}. Although counts IV and V have overlapping factual issues, they pertain to different shares of stock and implicate different contractual rights. Count IV pertains to the 314,640 shares which IMC promised to register and which subsequently became the subject of the alleged accord. Count V pertains to the 326,293 shares not subject to the registration promise and arises under paragraph 14.3 of the APA (the "further assistance" clause). Under SEC rules, these latter shares became alienable after the plaintiffs held them for one year (subject to the current dispute over whether an opinion letter was required).

Because material factual disputes exist under both counts, I deny the plaintiffs' motion for summary judgment. With regard to count IV, there are factual disputes over whether IMC and the plaintiffs reached an accord and whether IMC performed under its terms.^{FN5} Assuming that the parties agreed that on August 19, 1998 IMC would deliver to the plaintiffs \$5.4 million worth of saleable shares, the parties, in essence, dispute the meaning of "saleable." IMC argues that the shares were saleable because the plaintiffs could initiate a sale (and thereby protect their market price), even though they would not receive sale proceeds until an opinion letter issued. Padgett Aff. ¶¶ 7-10; Legler First Aff. ¶¶ 3-7; Legler Second Aff. ¶ 8. I think a reasonable juror could reach this conclusion. If it did, it could determine that IMC did not breach the accord (assuming one is found), since IMC transferred to the plaintiffs the shares of stock.^{FN6}

^{FN5}. Although the subject has been briefed in both the present and earlier motions, I reach no conclusion on whether the parties reached an accord. An accord settles a pre-

existing claim by a substituted performance. Jacksonville Elec. Auth. v. Draper's Egg & Poultry Co., 557 So.2d 1357, 1358 (Fla.1990). The substituted performance must differ from that claimed due. *Id.* at 1359. I leave for trial whether the two considerations differed, although I note that proof at trial may make appropriate an order pursuant to Fed.R.Civ.P. 50(a)(1).

FN6. IMC argues that the plaintiffs are estopped from challenging the validity of the accord because they received a benefit under it. Whether or not the plaintiffs benefitted from the proposed accord depends on resolution of the same factual disputes underlying IMC's performance. Moreover, there is evidence that IMC released the "top off" shares from an account holding contingency payment shares, in which the plaintiffs already may have had an interest.

The plaintiffs have presented evidence indicating that the shares were not saleable without an opinion letter or without an assurance that the opinion letter would issue. Sutton Dep. at 63-64; Simpson Dep. at 93-95, 97-98, 113-15. If the jury adopted this interpretation, which I believe it could, it would raise additional disputes. If an assurance was necessary, a question arises as to whether Legler's phone call in late July or early August constituted an "assurance" allowing Alex. Brown to sell the shares in the absence of a written opinion letter. Legler Dep. at 263-65; Simpson Dep. at 108 (noting that a month's length of time after first "verbal" may require Alex. Brown to call issuer again before sale is authorized). If a written opinion letter was necessary, IMC would argue that completion of the plaintiffs' forms was a condition precedent to IMC's performance. Because Holman, Toomey and Sutton state in their depositions that the necessary paperwork had been completed, Sutton Dep. at 64; Holman Dep. at 101; Toomey Dep. at 196, a dispute arises as to whether Legler's failure to return phone calls from Alex. Brown representatives prevented the plaintiffs from performing the condition precedent by sending the information to IMC. Sutton Dep. at 55-56.

*4 Last, I think a reasonable jury could determine that saleable meant that on August 19, 1998, the plaintiffs would be able to convert their shares into \$5.4 million. There is considerable testimony on both sides equating the "benefit of the bargain" originally and in the alleged accord with allowing plaintiffs to acquire cash for their shares. Legler Dep. at 193; Pl.'s Mot. Summ. J. Ex. 16 ("Brian and Dick had bargained for the right to be able to convert half of the shares they received into cash;" parties discussed strategies "enabling Dick and Brian to monetize certain of their holdings"); Marvin. Aff. ¶ 6. If the jury adopted this interpretation, and because IMC admits that the plaintiffs could not recover sale proceeds until an opinion letter issued, I think the jury reasonably could find that IMC breached the proposed accord by not providing an opinion letter on August 19, 1998. In sum, there is testimony and evidence to support all these positions, and while a reasonable jury could agree with any one of them, I do not believe that they would be obligated to adopt any one of them. FN7 Accordingly, I deny the plaintiffs' motion for summary judgment.

FN7. Had the parties signed a written accord, questions of formation and interpretation might be easier. But the parties did not, meaning that their intent will guide construction of an accord. Because there is conflicting evidence on intent, it must go to the jury.

Count V involves similar issues. The defendants do not dispute their obligation under the APA to provide further assistance. Indeed, they argue that they stood ready to provide it. But disputes again arise as to the procedures for obtaining an opinion letter and whether Legler and IMC (and Holman and Toomey) followed this course. A jury will have to resolve these issues.

III.

The plaintiffs also assert two breach of contract claims arising under the employment agreements. First, they claim that IMC breached the agreements by failing to pay the plaintiffs the pro rated portion of the salary for August 1999, the month they were ter-

minated. Second, they claim that IMC breached the agreements by failing to pay them the amount of their salaries through August 2002, the remainder of the contractual term. Both parties move for summary judgment on these counts. I grant the plaintiffs' motion on both counts.

Holman and Toomey signed identical employment agreements. Paragraph 2 of the agreements states a five-year term, ending on August 1, 2002. Employment Agreement ("Emp.Agr.") ¶ 2. It also provides that IMC may terminate the agreement at any time for cause. *Id.* If termination is not for cause, IMC must pay Holman or Toomey "through the remaining term of the Agreement." Emp. Agr. ¶ 6. Paragraph 2 defines cause as "serious misconduct by the Employee in respect to his obligation to the Company or Employer." Emp. Agr. ¶ 2. The agreement provides examples of cause, which include:

(i) Employee's conviction of a felony ...; (ii) the perpetration by Employee of a common law fraud relating to the scope of Employee's employment or the business of the Company or Employer; (iii) the violation by Employee of any material term of this Agreement or the failure of Employee to perform the amount and quality of service to Employer reasonably expected of him, which violation is not cured or rectified after reasonable notice thereof and a reasonable opportunity to do so; or (iv) willful refusal to follow the Employer's policies and directives which violation is not cured or rectified after reasonable notice thereof and a reasonable opportunity to do so.

*5 Emp. Agr. ¶ 2. IMC argues that it terminated Holman and Toomey for three reasons: (1) they filed suit against it; (2) they did not follow underwriting guidelines; (3) CitiFinancial's acquisition of IMC, which ceased business operations. Florida law governs the agreement. Emp. Agr. ¶ 14.

I do not believe that the plaintiffs' lawsuit against IMC provided cause for termination. Paragraph 2 does not mention this contingency. Moreover, the plaintiffs' lawsuit does not fit the general category created by the listed definitions. Although the plaintiffs may not succeed on all their claims, I do not find them frivolous or fraudulent in any respect.^{FN8} Although IMC cites *DeMarco v. Publix Super Mar-*

kets, Inc., 360 So.2d 134 (Fla.Dist.Ct.App.1978), which allowed an employer to terminate an employee who filed a personal injury suit against the employer, the case is distinguishable because it did not involve an employment for term. The court held that the employer could terminate the employee because "[t]he employment agreement ... having been for an indefinite time, Publix could terminate [the employee] for any reason without incurring liability." *Id.* at 136. IMC did not employ Holman and Toomey at will; they had a contract for term. To allow IMC to discharge Holman and Toomey based on the lawsuit would be to insert a contractual term for which IMC did not bargain.

^{FN8} IMC seems to have understood that the lawsuit would have to be fraudulent in some way to fit the spirit of paragraph 2. In the termination letter, George Nicholas, IMC's Chief Executive Officer, justifies the termination, in part, because the plaintiffs filed "a lawsuit against the Company which is based upon false, fraudulent and malicious allegations." Pl.'s Mot. Summ. J. Ex. 19.

Moreover, even assuming that Holman and Toomey violated company underwriting guidelines, IMC cannot avail itself of this reason for cause because it did not adhere to the section's "notice and cure" provision.^{FN9} The agreement defines cause, in part, as failure "to perform the amount and quality of service to Employer reasonably expected" or "willful refusal to follow the Employer's policies and directives. Emp. Agr. ¶ 2. But termination is not proper under either prong unless the conduct "is not cured or rectified after reasonable notice thereof and a reasonable opportunity to do so." *Id.* Holman and Toomey have submitted affidavits indicating that IMC never informed them prior to termination of a violation of the company's underwriting guidelines. Holman Aff. ¶ 6; Toomey Aff. ¶ 6. Diana DiPino states she was never disciplined either. DiPino Aff. ¶ 4; DiPino Dec. ¶ 3. IMC counters with the affidavit of Timothy Griffin, the Vice President and Chief Underwriter for IMC, who states that both in writing and orally he and his staff informed Holman and Toomey of loan deficiencies. Griffin Aff. ¶ 5. IMC provides none of this correspondence, however, or testimony of those who

communicated with CMM. Nor does Griffin state he informed Holman and Toomey that a failure to rectify any deficiencies would result in termination. Although Griffin does provide a log of deficiencies on loans originated at CMM during the relevant time period, Griffin Aff. Ex. A, Diana DiPino states that IMC created this log after the fact. Moreover, she notes that calls regarding deficiencies were a "low priority" for her and the IMC underwriter with whom she communicated. They were simply a "routine loan review and exchange of written comments." DiPino Dec. ¶ 5. Holman likewise refers to the discussions as a "management tool" by which IMC and CMM reached decisions. Sometimes CMM's interpretations controlled; other times IMC's did. Holman Dep. at 195-96. Other evidence affirms this. DiPino received excellent performance reviews. DiPino Dec. Ex. A. There simply is no evidence that IMC brought to Holman or Toomey's attention serious loan deficiencies, the continuation of which would lead to their dismissal. Compare AHC Physicians Corp. v. Dulock, 504 S.E.2d 464, 465 (Ga.Ct.App.1998) (finding that an employer had complied with a notice and cure provision where it provided letters stating "more than mere criticisms" of employee's performance). In sum, I do not believe a reasonable juror could find that IMC complied with paragraph 2's "notice and cure" provision.

FN9. The plaintiffs have presented evidence rebutting IMC's argument that deficient performance prompted the discharge. They present the affidavits of Diana DiPino (the Senior Underwriter at CMM during the relevant time period) and Frank Antico (the Vice President of Operations, who supervised DiPino), neither of whom was discharged or disciplined for poor underwriting at CMM. DiPino Aff. ¶ 4; DiPino Dec. ¶ 3; Antico Aff. ¶ 4. Moreover, there is no dispute that IMC had its own "on site" underwriter at CMM as of January, 1999 and that he approved all of CMM's loans after that time. Yet IMC did not terminate the plaintiffs until either months later.

*6 Last, IMC argues that it had cause to terminate the plaintiffs after CitiFinancial acquired IMC in July of

1999. It relies on Telesphere Int'l, Inc. v. Scollin, 489 So.2d 1152 (Fla.Dist.Ct.App.1986), in which an employer hired an employee specifically to market overseas a hotel call accounting system. *Id.* at 1153. The employer subsequently abandoned the project and terminated the employee. *Id.* The court held that the project's end provided "cause" for terminating the employee. But there was no formal employment contract in that case, only a letter agreement allowing the employer to terminate, among other reasons, "for cause." *Id.* The letter did not contain a term of employment nor did it define "cause." *Id.* The present agreement, which provided a five-year term, defined cause and focused on egregious job-related conduct by the plaintiffs. It did not contain a cessation of business clause. Compare Monte Carlo Dev. & Mgmt. Corp. v. Montgomery, 510 So.2d 1007, 1008 (Fla.Dist.Ct.App.1987) (construing a cessation of business provision in a contract involving a term of employment). Thus, I find that a reasonable jury could not find that IMC terminated the plaintiffs for cause.

Although I grant the plaintiffs' motion for summary judgment on count VIII, I do not award their requested damages. Paragraph 6 provides for payment only of the plaintiffs' "base salary" for the term August 1999 to August 2002. Emp. Agr. ¶ 6. Benefits for this period are not recoverable.

I also grant the plaintiffs' motion for summary judgment on count VII. The agreement clearly provides for pro rata payment of Holman and Toomey's August 1999 salary. Emp. Agr. ¶ 3(a). Again, however, it provides for payment only of the base salary, and not the benefits that the plaintiffs request. Accordingly, the plaintiffs may recover only the pro rata base salary payment.

I calculate the total recovery under counts VII and VIII as three years of salary for each plaintiffs (August 1, 1999 to August 1, 2002). At \$300,000 per year, this equals \$1.8 million.

IV.

The plaintiffs also filed a Motion to Amend the Amended Complaint. They ask to include a claim for

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fraud, alleging that Legler represented to them after September 9, 1997 that their 314,640 shares would be registered when he had no intention to register them. I grant the motion.

Under Fed.R.Civ.P. 15(a), leave to amend the complaint "shall be freely given when justice so requires." See Foman v. Davis, 371 U.S. 178, 182 (1962) (the mandate in Fed.R.Civ.P. 15(a) "is to be heeded"). Leave should be denied only when "the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile." Edwards v. City of Goldsboro, 178 F.3d 231, 242 (4th Cir.1999) (citation omitted). This case does not fit these circumstances. The defendants argue that the plaintiffs have known about the post-closing fraud theory since May 3, 1999. In a letter bearing that date, Stuart Marvin informed the plaintiffs' counsel that outside securities counsel had advised IMC that registering the shares would create "substantial difficulty for IMC because of a number of other pending transactions." Def.'s Mem. Opp'n Pl.'s Mot. to Amend Am. Compl at 5. Alternatively, they note that the plaintiffs have had notice to amend since the May 25, 2000 deposition of Peter Kolevzon. Kolevzon testified that he advised Legler of the problems with registering the plaintiffs' stock in September 1997. The plaintiffs argue that discovery on the debt offering did not end until the August 11, 2000 deposition of Ashley Robert Ise. The plaintiffs filed their motion on September 8, 2000. Although I am troubled by the plaintiffs' failure to file their motion sooner, I do not believe this time line suggests bad faith.

*7 More importantly, absent prejudice, possible delay does not mandate a denial of leave. Deasy v. Hill, 833 F.2d 38, 41 (4th Cir.1987) ("Delay alone, without prejudice, does not support the denial of a motion for leave to amend"). I do not believe the amendment prejudices the defendants. First, the proposed amendment relates to facts that the original complaint contained. Com pl. ¶¶ 29-39; see Edwards, 178 F.3d at 243 (abuse of discretion for district court to deny motion to amend where amendment involved facts learned during discovery regarding matters contained in the complaint). Second, the defendants inquired at length about post-closing conversations between Leg-

ler and Toomey (and Holman) during Holman's deposition, Toomey's February deposition and Toomey's continued deposition on August 17, 2000.FN10 See Pl.'s Reply to Def.'s Opp'n to Mot. to Amend Ex. A, B, D. Compare Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc., 43 F.3d 922, 940 (4th Cir.1995) (not an abuse of discretion for court to deny leave to amend where proposed amendment concerned a defense that was "not the subject" of earlier discovery); Remington Arms Co. v. Modern Muzzleloading, Inc., 1998 WL 1040949, at *2 (M.D.N.C. Dec. 17, 1998) (denying leave to amend where no discovery taken on subject of amendment). Third, the plaintiffs filed the motion before summary judgment and prior to trial. Indeed, no trial date has been set. Compare Deasy, 833 F.2d at 41 (affirming denial of leave where amendment proposed "right before trial").

FN10. The defendants claim prejudice because they did not seek rulings on privilege assertions by two witnesses, Jordan Bailowitz and Steve Owen, whose testimony now is relevant to the proposed amendment. They may do so by motion. Moreover, to the extent that the defendants require additional discovery, I will entertain motions for a reasonable extension of discovery.

Nor does the claim appear futile. A cursory review of the affidavits reveals evidence to support the plaintiffs' amended theory of fraud. Although the defendants suggest that the plaintiffs cannot show reliance, I will not at this time treat the defendants' motions as ones for failure to state a claim. If they wish to brief this issue in such a motion or in a motion for summary judgment, they may, of course, do so. Accordingly, I grant the plaintiffs' motion to amend the second amended complaint.

An order effecting the rulings herein shall be entered forthwith.

ORDER

For the reasons stated in the foregoing memorandum, it is, this 9th day of January, 2001, hereby ORDERED that:

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Not Reported in F.Supp.2d, 2001 WL 21222 (D.Md.)

(Cite as: Not Reported in F.Supp.2d)

1. IMC's and Legler's motions for summary judgment on counts I, II and III are granted;
2. The plaintiffs' motion for summary judgment on counts IV and V is denied;
3. IMC's cross-motion for summary judgment on counts VII and VIII is denied;
4. The plaintiffs' motion for summary judgment on counts VII and VIII is granted and judgment is entered for the plaintiffs in the amount of \$1.8 million;
5. The plaintiffs' motion to amend the amended complaint to state a count IX is granted;
6. The plaintiffs' motion for leave to file declarations is granted.

D.Md.,2001.

Holman v. IMC Mortg. Co.

Not Reported in F.Supp.2d, 2001 WL 21222 (D.Md.)

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